

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF MICHIGAN**

**UNITED STATES OF AMERICA** )  
    **ex rel. DAVID FELTEN,** )  
    **M.D., Ph.D., and** )  
**STATE OF MICHIGAN** )  
    **ex rel. DAVID FELTEN,** )  
    **M.D., Ph.D.,** )  
 )  
    **Plaintiff-Relator,** )

**v.** )

**WILLIAM BEAUMONT** )  
**HOSPITALS; ACADEMIC HEART** )  
**AND VASCULAR, PLLC;** )  
**BEAUMONT ONCOLOGY** )  
**NETWORK; ASSOCIATED RETINAL** )  
**CONSULTANTS; CINDY** )  
**GRINES, M.D.; DAVID E. HAINES,** )  
**M.D.; ROBERT D. SAFIAN, M.D.;** )  
**JAMES A. GOLDSTEIN, M.D.;** )  
**SIMON R. DIXON, M.B.Ch.B.;** )  
**GEORGE S. HANZEL, M.D.;** )  
**ALVARO MARTINEZ, M.D.; JEFF** )  
**MARGOLIS, M.D.; DI YAN, PH.D.;** )  
**DAVID JAFFRAY, M.D.; FRANK** )  
**VICINI, M.D.; DAVID WONG, M.D.;** )  
**GEORGE WILLIAMS, M.D.;** )  
**MICHAEL TRESE, M.D.; RALPH** )  
**MARGULIS, M.D.; KENNETH** )  
**PETERS, M.D.; PETER LEWITT,** )  
**M.D.; PETER MCCULLOUGH, M.D.;** )  
**KEN MATZICK, M.D.; CHARLES** )  
**SHANLEY, M.D.; STEWART** )  
**GORDON, M.D.; ANANIAS DIOKNO,** )  
**M.D.; WILLIAM O'NEILL, M.D.;** )  
**THOMAS MCASKIN; and GENE** )  
**MICHALSKI;** )  
 )  
    **Defendants.** )

**Civil Action No. 2:10-cv-13440**  
**Jury Trial Demanded**

**FILED IN CAMERA AND**  
**UNDER SEAL**

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**COMPLAINT**

Pursuant to 31 U.S.C. § 3730(b)(1) and M.C.L. 400.601a, Relator David L. Felten, for himself and on behalf of the United States of America and the State of Michigan, by his attorneys, Bothwell Bracker & Vann, P.C., bring this civil action under the False Claims Act, 31 U.S.C. § 3729 *et seq.* and the Michigan Medicaid False Claims Act, M.C.L. 400.601 *et seq.*

## **INTRODUCTION**

Relator David Felten assumed the post of Medical Director of the Beaumont Research Institute in 2005 and was subsequently appointed to the newly created position of Vice President, Research. Almost immediately, it became apparent that there was a host of compliance issues at the hospital. Relator's efforts to correct these issues were met with hostility, push-back, and counterattacks from his fellow physicians. Relator has fought a hard, five-year battle to bring Beaumont into compliance with government regulations. During that time, he has grown increasingly skeptical that hospital administration has any interest in correcting the myriad of illegalities he discovered on a near weekly basis. Relator has kept up a constant and vigorous campaign to improve the system's compliance, particularly in the research arena. However, it has become obvious that there has been no significant progress toward correction. Indeed, new approaches have recently been proposed that are just as non-compliant as the existing ones. To support his claims of fraudulent conduct, Relator alleges as follows:

## **JURISDICTION AND VENUE**

1. This action arises under 31 U.S.C. § 3729 *et seq.*, also known as the False Claims Act ("FCA"), 42 U.S.C. § 1320a-7b(b)(1)-(1), also known as the Anti-Kickback Statute, and the Michigan Medicaid False Claims Act, M.C.L. 400.601 *et seq.*, to recover treble damages and civil penalties on behalf of the United States of America and the State of Michigan arising out of Defendants' violations of the FCA and the Michigan Medicaid FCA.

2. Under § 3732 of the FCA, this Court has jurisdiction over actions brought under the FCA. Furthermore, jurisdiction over this action is conferred on this Court by 28 U.S.C. § 1331 because this civil action arises under the laws of the United States.

3. This Court has supplemental jurisdiction over all other claims set forth in this Complaint because these claims are so related to the claims arising under the Federal False Claims Act that they form part of the same case or controversy. *See* 28 U.S.C. § 1367.

4. Venue is proper in this district pursuant to § 3732(a) of the FCA, because at all times material hereto, Defendants regularly conducted substantial business in the State of Michigan and maintained permanent employees and offices in the State of Michigan, within this judicial district. Additionally, venue is proper in this district pursuant to 28 U.S.C. § 1391(b)(1)-(2).

#### **FILING UNDER SEAL**

5. Under the Act, this Complaint is to be filed in camera and remain under seal for a period of at least sixty days and shall not be served on Defendants until the Court so orders. The Government may elect to intervene and proceed with the action within sixty days after the Government receives the Complaint.

6. As required by the False Claims Act, Relator voluntarily submitted a confidential written disclosure statement (subject to the attorney client privilege,

the common interest privilege and the joint prosecutorial privilege) to the United States Government via the United States Attorney's Office in the Eastern District of Michigan and the Attorney General's office, containing material evidence and information in his possession pertaining to the allegations contained in this Complaint.

### **PARTIES**

7. Relator David Felten, M.D., Ph.D., is an internationally renowned research physician whose contributions to neuroscience helped to establish the field of psychoneuroimmunology (brain, behavior and immunity). His distinguished career as a researcher includes such highlights as a MacArthur Foundation Prize Fellowship, two nominations for a Lasker Prize, and two 10-year peer review-based MERIT awards from two separate institutes of the National Institutes of Health (National Institute on Aging, National Institute of Mental Health). He is a resident of Ontario County, New York and has a second residence in Troy, Michigan (Oakland County). Relator currently holds the title of Vice President, Research and Medical Director of the Research Institute ("RI") at William Beaumont Hospitals, as well as Associate Dean for Research at the Oakland University William Beaumont School of Medicine.

8. William Beaumont Hospitals (collectively "Beaumont") is a three-hospital system in Southeast Michigan with an ambulatory care network, many

peripheral outpatient centers, nursing home and home-health components, and a system of physician offices. Beaumont is composed of Royal Oak, Troy, and Grosse Pointe (formerly Bon Secours Hospital) Hospitals. In all, the system has about 1,744 beds.

9. Even after recent cuts necessitated by the struggling economy, Beaumont has a \$2 billion per year operating budget, a capital budget of \$166 million for 2010, more than 18,000 employees, and close to 3,000 associated physicians.

10. Beaumont employs approximately 450 full time employed physicians and 2,500 private practitioners credentialed to have admitting privileges at one or more of the Beaumont hospitals.

11. Currently, Beaumont ranks second in the nation for the number of Medicare patients who are provided services.

12. Academic Heart and Vascular PLLC (“Academic Heart”) is a professional corporation organized under the laws of Michigan that primarily resides and conducts business in Oakland County, Michigan. Academic Heart is one cardiology practice group associated with the Beaumont system.

13. Defendant doctors Cindy L. Grines, M.D.; David E. Haines, M.D.; Robert D. Safian, M.D.; James A. Goldstein, M.D.; Simon R. Dixon, M.B.Ch.B; and George S. Hanzel, M.D. (collectively “the Cardiologists”) are cardiologists at

Beaumont and members of Academic Heart, each of whom has received kickbacks and inappropriate remuneration.

14. Beaumont Oncology Network (“BON”) is a professional corporation organized under the laws of Michigan, which primarily resides and conducts business in Oakland County, Michigan. BON was organized as a service corporation to organize oncologic services for all Beaumont oncologists.

15. Defendant doctors Alvaro Martinez, M.D.; Jeff Margolis, M.D.; Di Yan, Ph.D.; David Jaffray, M.D.; Frank Vicini, M.D.; and David Wong, M.D. (collectively “the Rad Onc doctors”) are radiation oncologists or physicists practicing and/or researching at Beaumont and/or with BON, each of whom has received inappropriate incentives and misappropriated Government funds and/or intellectual property.

16. Associated Retinal Consultants (“ARC”) is a Michigan corporation, organized as a private practice in ophthalmology and to facilitate research in ophthalmology.

17. Defendant doctors George Williams, M.D., and Michael Trese, M.D., (collectively “the Ophthalmologists”) are members of ARC and practice at Beaumont and/or ARC, both of whom have received inappropriate incentives.

18. Defendants Ralph Margulis, M.D.; Kenneth Peters, M.D.; Peter LeWitt, M.D.; Peter McCullough, M.D.; Ken Matzick, M.D.; Charles Shanley,

M.D.; Stewart Gordon, M.D.; Ananias Diokno, M.D.; and William O'Neill, M.D. are physicians presently or formerly associated with Beaumont, each of whom has received kickbacks and illegal incentives.

19. Defendant Thomas McAskin is Chief Legal Counsel for Beaumont and has authored and engaged in much of the illegal and fraudulent acts described herein.

20. Defendant Gene Michalski is Chief Executive Officer of Beaumont, formerly served as the Chief Operating Officer for Beaumont, and has authored and engaged in much of the illegal and fraudulent acts described herein.

21. All Defendants named herein transact business in Oakland County, Michigan and are subject to the personal jurisdiction of the Court.

### **BACKGROUND**

22. In mid-2007, Beaumont saw a drop in revenues relating to the loss of medical insurance programs associated with the auto industry. The change in payer mix and internal financial inefficiencies were internally quantified initially as a patient revenue loss of \$1,600 per every Medicare patient who came to the hospital, with Medicare now representing almost 50% of all patients.

23. In addition, the crash of the credit market, the state of southeast Michigan's economy, and market share competition with other hospitals led Beaumont's leadership to recognize that they must cut millions from their

operating budget and make other massive cuts to a capital budget originally set at over \$1 billion per year.

24. In response to this changing financial picture, Beaumont hired Sam Flanders, M.D., as the Chief Safety Officer. Dr. Flanders was asked to conduct assessments such as costs per DRG, costs per physician, systemic inefficiencies, and other financial and safety metrics in order to suggest improvements.

25. Any use of the resulting metrics, however, has been stymied by the same culture that Relator has been battling – that of incentivizing Beaumont’s physicians.

26. As Vice President of Research and a trusted member of the Beaumont Leadership Council, the Corporate Medical Leadership Group, and the Medical Executive Council, Dr. Felten has been part of countless internal meetings in which these troubling physician incentives were discussed. Some of them, such as fraudulent roll up of research time and effort to the Cost Report, relate to matters he personally has attempted to “clean up” in the RI. Other matters, such as the ongoing kickbacks for cardiologists and oncologists, are openly acknowledged as a problem, but only because of the financial bind created by attempting to maintain the same level of physician compensation that is expected.

27. Beaumont physician salaries and contracts are managed through Beaumont Professional Services (“BPS”), an entity formerly run by Tom

Thompson and John Meloeny, with input from the Chief Legal Officer (Tom McAskin) and the Chief Medical Officer (Ron Irwin, M.D., through late 2006, then Ananias Diokno, M.D.).

28. From 2005 through early 2008, Relator met weekly with Tom Thompson, who had supervised the previous Administrative Director of the Research Institute, Veronica Decker, prior to Relator's arrival.

29. In these meetings, Felten and Thompson spoke frankly about the arrogant and non-compliant behavior of some of the researchers and the challenges inherent in trying to "clean up" the myriad of problems in the Research Institute which Veronica Decker, Jack DeChellis (Director of Finance and Grants & Contracts), and Relator had inherited.

30. During those meetings, Thompson stated repeatedly that the physician contracts "were a mess." Sometimes the contracts could not be found, some contained special deals that were blatantly inappropriate or illegal, and there was no consistent rule or policy about physician compensation and perks.

31. When Thompson retired in the spring of 2009, he was replaced by Karen Turner.

32. Relator spoke with Ms. Turner on several occasions, and learned that she was appalled at the disarray of the physician contracts. Turner stated that not

only were the contracts a mess, they were riddled with illegalities and potential legal/ethical disasters for Beaumont.

33. In fact, Ms. Turner was so appalled that she left the position at Beaumont after only a few months and told Relator privately that she simply could not be a party to BPS's illegalities.

34. Upon her departure in the summer of 2009, Tom Thompson was brought back on a part time basis to continue at BPS, and Charles Shanley, M.D., was promoted to Associate CMO and placed in charge of physician contracts and the newly-hatched CARTS program (discussed below).

35. Around the first quarter of 2009, Beaumont leadership decided to hire outside consultants to deliver the message that the structure at Beaumont was going to have to change in order for the system to remain profitable. Consulting company FTI Healthcare ("FTI") was hired around March 2009 to assist Beaumont with Case Management and Clinical Resource Management (CRM), physician funds flow ('CARTS'), and organization structure."

36. Kathy Herron, an FTI consultant, was appointed interim director of BPS.

37. FTI's evaluation of Beaumont's physician contract system was devastating. The report was presented via PowerPoint to the Beaumont Leadership Council on September 14, 2009.

38. FTI's consultants identified missing contracts, systematic lack of job descriptions, a morass of special deals, and a host of "Medical Directorships" for which there were no job descriptions or expectations.

39. Consultants at the September 14, 2009 meeting verbally described the situation with midlevel providers as a "serious OIG matter" that needed immediate attention.

40. As to physician compensation, FTI found that Beaumont salaries generally do not match productivity standards and that "no standard performance evaluation metrics exist."

41. FTI further found that bonus or incentive compensation at Beaumont is highly variable and that little or no outcome data have been used to evaluate job performance or activities related to directorships.

42. In addition, Beaumont's cash collection for physician activities is well below that of Beaumont's benchmarked institutions in the region, supporting Relator's understanding that many of the highly compensated physicians are permitted to retain monies from their clinical practices, despite being full time Beaumont employees.

43. FTI also reported that there are too many physicians supposedly employed by the hospital but who have no job descriptions, metrics, or productivity outcomes.

44. In all, a breathtaking equivalent of 132 full time employee (FTE) physicians could not be accounted for in terms of deliverables, accounting for \$16.3 million per year (out of \$50.5 million per year in total physician Part A FTEs).

45. According to FTI's investigation, payment for medical directorships account for 56.1 full time employees and cost about \$12.4 million per year – an amount \$3.2 million over benchmark for Beaumont.

46. This would be bad enough if the directorships had job descriptions with accountability, but FTI described Beaumont's situation as "excess numbers of Medical Directorships with no job descriptions and few deliverables."

47. In a follow up conversation, FTI consultant Kathy Herron informed Relator that many of the current physician contract arrangements, which she had reviewed, are "tainted" and appear to be "in violation" of Medicare and Medicaid laws and regulation.

48. Beaumont's medical directors are not required to keep logs documenting that services were provided, do not keep track of their hours, do not have work plans, and cannot show that they have done anything in exchange for compensation.

49. FTI recommended a total restructuring of Medical Directorships with job description templates, elimination of inappropriate and gratuitous

Directorships, and establishing annual goals, objectives, and performance appraisals for those that remain.

50. As a global solution, FTI proposed the “CARTS” model. The CARTS program is intended to clearly define physician salary components and expectations by breaking each physician’s tasks into the areas of Clinical, Administrative, Research, Teaching, and Special projects. Each area is to have defined outcomes and a defined compensation structure.

51. Under CARTS, each physician’s salary will be budgeted according to the percentages of his or her CARTS Work Job Description (“WJD”).

52. Not surprisingly, physicians were vocal in their preference for Beaumont’s existing compensation structure. Dr. Shanley (Executive Vice President in charge of implementing CARTS) told Relator at a BioBank advisory meeting on February 18, 2010 that the physicians viewed CARTS as “taking away” their perks.

53. Shanley further noted that other doctors were beginning to attack him as the administrative representative of the program and that he hated to be “the bad guy” in this process. Shanley seemed unconcerned, however, with the illegality of the arrangements. He considers its correction as more of a financial issue.

54. An executive retreat was held on June 23, 2010 to discuss CARTS implementation. The retreat included a lengthy session to discuss the Research

(“R”) component. Relator bluntly described to the attendees what he considers to be misrepresentation of research time on both the Medicare Cost Report and the Medicare Time and Effort Report sheets for physicians. Specifically, research time is not reported and deducted from total time and effort that is “rolled up” to the Cost Reports annually.

55. He was silenced by Bruce Quinlan (FTI consultant) and Michele Barnard (Diokno’s personal assistant) and criticized for being “resistant to change.” Relator responded that he was not resistant to change, but was very resistant to Medicare fraud.

56. At that same meeting, Bruce Quinlan proposed a revision to the “R” component for CARTS by proposing “incentive” bonuses based on the total amount of grant money brought in. Quinlan proposed a concomitant phase out of the supposedly unnecessary Medicare Time and Effort Reports for calculating research commitments.

57. Relator and Scott Flowerday (Chief Signatory of Beaumont’s Cost Report) both protested vigorously but were ignored. It now appears that an already flawed and inappropriate system is going to be replaced by an “R” component that is even more non-compliant and that encourages Medicare fraud.

58. Over the nine months since FTI consultants first revealed their findings, Relator came to realize that Beaumont has no intention of correcting these illegal behaviors.

59. In fact, investigation revealed considerable evidence that many problems Relator had been assured were already taken care of actually have not been addressed at all. In addition, Relator has uncovered some additional non-research issues that appear to be serious violations.

60. As Relator has brought these matters to the attention of the CMO and other top administrative leaders, his corporate role has been gradually diminished, his influence has been marginalized, his ideas and suggestions have been disregarded, and his decisions in regulatory and compliance arenas gradually have been sidetracked.

61. One clinical chief told Relator outright that, “You need to learn to just go along with the physicians, help them to do what they want, and not create waves or try to be a crusader. If you keep creating waves, you will be destroyed.”

### **LEGAL AND REGULATORY FRAMEWORK**

62. **The Anti-Kickback Statute**, 42 U.S.C. § 1320a-7b(b) (“AKS”), arose out of Congressional concern that if those who influence healthcare decisions were allowed to have a financial stake in selection of healthcare goods and

services, their judgment might be tainted, resulting in goods and services being provided that are medically unnecessary, of poor quality, or even harmful.

63. To protect the integrity of government programs, in 1972 Congress enacted a *per se* prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback gave rise to overutilization or poor quality of care, strengthening that statute in 1977 and again in 1987. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

64. Among other provisions, the AKS makes criminal certain types of remunerative arrangements:

(b) Illegal remunerations.

(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$ 25,000 or imprisoned for not more than five years, or both.

(2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$ 25,000 or imprisoned for not more than five years, or both.

42 U.S.C.S. § 1320a-7b.

65. Violation of the AKS subjects the perpetrator to exclusion from federal health care programs, civil money penalties of \$50,000 per violation and three times the amount of remuneration paid. 42 U.S.C. § 1320a-7(b)(7) and (a)(7).

66. **The Stark Laws** are made up three separate provisions which govern physician self-referral for Medicare and Medicaid patients. Under the Stark Laws, physicians are prohibited from referring a patient to a medical facility in which they have a financial interest. Given the physician's position to benefit from the

referral there is both an inherent conflict of interest, and potential for over-utilization of services. In addition, such referrals could limit competition. Stark regulations may be found at 42 C.F.R. § 411.350 through § 411.389.

67. Stark I was included as a provision in the Omnibus Budget Reconciliation Act of 1989 and barred self-referrals for clinical laboratory services under the Medicare program, effective January 1, 1992. Stark I also included a series of exceptions to accommodate legitimate business arrangements. Stark II, contained in the Omnibus Budget Reconciliation Act of 1993 (OBRA 1993), expanded the restriction to a range of additional health services and applied it to both Medicare and Medicaid.

68. The Designated Health Services ("DHS") covered by the Stark Laws include clinical laboratory services; physical therapy; occupational therapy; radiology and imaging services; radiation therapy and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment and supplies; prosthetics, orthotics and prosthetic devices; home health care and supplies; outpatient prescription drugs; and inpatient and outpatient hospital care.

69. Stark broadly defines "referral" to include a request by a physician for an item or service payable under Medicare or Medicaid (including the request by a physician for consultation with another physician as well as any test/procedure

ordered/performed by such other physician), or a request by a physician for the establishment of a care plan to include provision of a DHS.

70. CMS has provided certain exceptions to the AKS and Stark laws, in order to permit legitimate relationships between physicians and related professionals and institutions. Beaumont, however, has failed to avail itself of any of the exceptions.

71. An agreement for the **rental of office space** is excepted if the lease agreement meets several requirements: Per 42 C.F.R. § 411.357(a), such an agreement is permitted if (a) the agreement is in writing, signed by the parties, and specifies the premises covered; (b) the term of the lease is for at least one year; (c) the amount of space rented is reasonable and necessary for the legitimate business purposes of the business involved, and is used exclusively by the lessee (except that pro rata payments for use of common areas is permitted); (d) the rental amount for the term of the lease is set in advance and is consistent with fair market value (“FMV”) for the property; (e) the agreement would be commercially reasonable even if no referrals were made between the lessee and lessor. 42 U.S.C. § 1395nn(e)(1)(A); 42 C.F.R. § 411.357(a). A month-to-month rental for up to at least one year will satisfy this exception, provided that the holdover rental is on the same terms and conditions as the immediately preceding agreement. 42 C.F.R. § 411.357(a) and (f) Rental amount may not be determined in a manner that takes

into account the volume or value of any referrals or other business generated between the parties. The rental amount may not be determined using a formula that is based on a percentage of revenue or per unit of service rental charge. 42 C.F.R. § 411.357(a)(5)(ii); 73 Fed. Reg. 48,752 (Aug. 19, 2008).

72. FMV is defined statutorily to mean “the value in arm’s length transactions, consistent with the general market value”. 42 U.S.C. § 1395nn(h)(3).

73. **An agreement to rent equipment** likewise is excepted if the rental agreement meets the same requirements as set forth above in the exception for rental of office space.

74. Similarly, payment by an employer to a physician (or immediate family member) who has a bona fide **employment relationship** with that employer is not a “compensation arrangement” prohibited by Stark if it is for identifiable services, is for an amount consistent with FMV, and is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician, and the agreement would be commercially reasonable even if no referrals were made to the employer. 42 U.S.C. § 1395nn(e)(2); 42 C.F.R. § 411.357(c).

75. In 42 U.S.C. § 1395nn(b)(4), CMS created a regulatory exception for **Academic Medical Centers** (“AMCs”) due to the interrelated nature of functions

among faculty, medical centers, and teaching institutions, and the education roles of faculty in such centers.

76. However, CMS still requires certain conditions to be satisfied in order to prevent fraud or abuse, and so prohibition on referrals and billing will not apply to services provided by an AMC only if the referring physician (a) is a bona fide employee of a component of an AMC; (b) is licensed to practice medicine in the state; (c) has a bona fide faculty appointment at the affiliated medical school or the accredited academic hospital; and (d) provides either substantial academic or clinical teaching services for which s/he receives compensation as part of the employment relationship with the AMC. 42 C.F.R. § 411.355(e)(1)(i).

77. Moreover, total compensation for the year must be set in advance and must not exceed FMV in the aggregate for the services provided. Compensation arrangements may not take into consideration the volume or value of any referrals or other business generated. 42 C.F.R. § 411.355(e)(1)(ii) In addition, the compensation arrangement must not violate the AKS, and billing and claims submissions must be proper. 42 C.F.R. § 411.355(e)(1)(iv).

78. The AMC itself also must meet certain conditions in order for the exception to apply: (a) all transfers of money between components of the AMC must directly or indirectly support the missions of teaching, indigent care, research, or community service; (b) the relationship among the components of the AMC

must be memorialized in writing(s) duly adopted by the governing body of each component; and (c) all money paid to referring physicians for research must be used solely to support bona fide research or teaching. 42 C.F.R. § 411.355(e)(1)(iii).

79. Title XVIII of the Social Security Act, 42 U.S.C. § 1395, *et seq.*, establishes the Health Insurance for the Aged and Disabled Program, popularly known as the **Medicare program**. The Secretary of the United States Department of Health and Human Services (“HHS”) administers the Medicare Program through the Centers for Medicare and Medicaid Services (“CMS”).

80. **Medicare Part A** provides basic insurance for the costs of hospitalization and post-hospitalization care. 42 U.S.C. § 1395c-1395i-2 (1992). **Medicare Part B** is a federally subsidized, voluntary insurance program that covers the fee schedule amount for laboratory services. 42 U.S.C. §§ 1395(k), 1395(i), 1395(s).

81. Reimbursement for Medicare claims is made by the United States through CMS. CMS, in turn, contracts with private insurance carriers to administer and pay Medicare Part B claims from the Medicare Trust Fund. 42 U.S.C. § 1395(u). In this capacity, the carriers act on behalf of CMS. 42 C.F.R. § 421.5(b). Most hospitals, including Beaumont, derive a substantial portion of their revenue from the Medicare program.

82. In order to receive Medicare funds, enrolled suppliers, including Defendants, together with their authorized agents, employees, and contractors, are required to abide by all the provisions of the Social Security Act, the regulations promulgated under the Act, and all applicable policies and procedures issued by the states.

83. Among the rules and regulations which enrolled suppliers, including Defendants, agree to follow are to: (a) bill Medicare Carriers for only those covered services which are medically necessary; (b) not bill Medicare Carriers for any services or items which were not performed or delivered in accordance with all applicable policies, nor submit false or inaccurate information relating to provider costs or services; (c) not engage in any act or omission that constitutes or results in over-utilization of services; (d) be fully licensed and/or certified under the applicable state and federal laws to perform the services provided to recipients; (e) comply with state and federal statutes, policies and regulations applicable to the Medicare Program; and (f) not engage in any illegal activities related to the furnishing of services to recipients.

84. Under the Medicare Program, CMS makes payments retrospectively (after they are rendered) to hospitals for inpatient services. In order to establish a hospital's eligibility to participate in the program, Medicare enters into provider agreements with a given hospital. However, the contract between Medicare and

the hospital is not to provide particular services for particular patients. Any benefit from those services is derived solely by the patients and not by the U.S. or the Medicare program.

85. **Resource-Based Relative Value Scale (RBRVS)** has been used since the Omnibus Budget Reconciliation Act of 1989 to determine how much money medical providers should be paid. It is currently used by CMS and by nearly all Health maintenance organizations (HMOs). The RBRVS assigns procedures performed by a physician or other medical provider relative value units (“RVUs”). Total RVUs for a given procedure/CPT code is composed of three separate factors: physician work (52%), practice expense (44%), and malpractice expense (4%). The RVUs assigned to CPT codes change from year to year.

86. RVUs are then adjusted by geographic region. This value is then multiplied by a fixed conversion factor, which changes annually, to determine the amount of payment.

87. To assist with the administration of Medicare Part A, CMS contracts with fiscal intermediaries (“FIs”) pursuant to 42 U.S.C. § 1395h. These FIs are typically insurance companies, and are responsible for processing and paying claims and for audits of a provider’s cost reports. Upon discharging a Medicare beneficiary, the hospital submits claims for interim reimbursement for items and services provided during the beneficiary’s stay. 42 C.F.R. §§ 413.1, 413.60,

413.64. Hospitals use CMS Form UB-92 (formerly HCFA Form UB-82) to submit these interim claims.

88. In order to receive payment from Medicare, CMS requires hospitals to annually submit CMS-2552, known as a Hospital Cost Report. Cost Reports are the final claim made to a FI for payment for services provided to Medicare beneficiaries.

89. The **Cost Report**, which is filed with the FI, states the total amount that the hospital believes it is due for the year from CMS. *See* 42 U.S.C. § 1395g(a); 42 C.F.R. § 413.20. *See also* 42 C.F.R. § 405.1801(b)(1). CMS relies on the Cost Report to determine whether it owes the hospital more than has been paid through interim payments, or whether the hospital has been overpaid and must reimburse the Medicare program. 42 C.F.R. §§ 405.1803, 413.60, and 413.64(f)(1).

90. Medicare payments for inpatient hospital services are determined by the claims submitted by the provider for particular patient discharges (specifically listed on UB-92s/UB-82's) during the course of the fiscal year. On the Cost Report, this liability for inpatient services is then totaled with any other Medicare liabilities owed to the provider. This total determines Medicare's true liability for services rendered to Medicare beneficiaries during the course of a fiscal year. From

this sum, the payments made to the provider during the year are subtracted to determine the amount due the Medicare program or the amount due the provider.

91. Medicare has the right to audit the Cost Reports and financial representations made by all of the Beaumont hospitals to ensure their accuracy and preserve the integrity of the Medicare Trust Funds. This right includes the right to make retroactive adjustments to Hospital Cost Reports previously submitted by a provider if any overpayments have been made. 42 C.F.R. § 413.64(f).

92. Every hospital's Cost Report contains a "Certification" that must be signed by the chief administrator of the provider or a responsible designee of the administrator. Prior to September 30, 1994, the responsible provider official was required to certify, in pertinent part:

*[T]o the best of my knowledge and belief, it [the Hospital Cost Report] is a true, correct and complete statement prepared from the books and records of the provider in accordance with applicable instructions, except as noted.*

(Form CMS-2552-81).

93. Thus, the provider was required to certify that the filed Hospital Cost Report is (1) truthful, i.e., that the cost information contained in the report is true and accurate; (2) correct, i.e., that the provider is entitled to reimbursement for the reported costs in accordance with applicable instructions; and (3) complete, i.e., that the Hospital Cost Report is based upon all known information.

94. The “applicable instructions” contained in the pre-September 1994 certification included the requirement that services described in the Cost Report complied with Medicare program requirements, including provision outlawing kickbacks, codified in 42 U.S.C. § 1320a-7b(b). The pre-September 1994 Hospital Cost Report (CMS-2552-81) reminded providers that “intentional misrepresentation or falsification of any information contained in this cost report may be punishable by law fine and/or imprisonment under federal law.”

95. On September 30, 1994, Medicare revised the certification provision of the Hospital Cost Report to add the following:

*I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.*

(Form CMS-2552-92).

96. Subsequently, in or about 1996, the Hospital Cost Report was revised again to include the following notice:

*Misrepresentation or falsification of any information contained in this cost report may be punishable by criminal, civil, and administrative action, fine and/or imprisonment under Federal law. Furthermore, if services identified in this report were provided or procured through the payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil and administrative action, fines and/or imprisonment may result.*

97. Under all versions of the CMS Form 2552 certification, the provider certified that services provided in the cost report were not infected by a kickback.

98. A hospital is required to disclose all known errors and omissions in its claims for Medicare reimbursement (including its cost reports) to its fiscal intermediary. 42 U.S.C. § 1320a-7b(a)(3) specifically creates a duty to disclose known errors in cost reports:

*Whoever...having knowledge of the occurrence of any event affecting (A) his initial or continued right to any such benefit or payment...conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized...shall in the case of such a...concealment or failure...be guilty of a felony.*

99. Each year, Beaumont submitted Hospital Cost Reports that falsely represented compliance with Medicare laws/regulations, including the Anti-Kickback Statute. These misrepresentations were material to the Government's decision to pay for services. In light of the foregoing, each CMS Form UB-92/UB-82 submitted by Beaumont under Medicare was a false claim.

100. In addition to the hospital fees billed by hospitals, physicians also bill for their services provided to Medicare patients. Physicians and physician groups submit form CMS-1500 (formerly HCFA-1500) for this purpose. The CMS-1500 claim form requires the physician to certify that the physician "understand(s) that payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal or State laws."

101. By submitting CMS-1500 forms, physicians and physician groups certify that they are eligible for participation in the Medicare program, and that they have complied with all applicable regulations and laws governing the program, including the Anti-Kickback Statute.

102. **Medicaid** is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled. The federal involvement in Medicaid is largely limited to providing matching funds and ensuring that states comply with minimum standards in the administration of the program. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding, which is called federal financial participation (“FFP”). 42 U.S.C. § 1396d(a)(1)-(2).

103. In many states, provider hospitals participating in the Medicaid program file annual cost reports with the state’s Medicaid agency, or its intermediary, in a protocol similar to that governing the submission of Medicare cost reports. Some states permit provider hospitals to file a copy of their Medicare cost report with the Medicaid program, which is then used by Medicaid or its intermediaries to calculate Medicaid reimbursement. In other states, provider hospitals must file a separate Medicaid cost report. In either case, providers incorporate the same type of financial data in their Medicaid cost reports as

contained in their Medicare cost reports and include data concerning the number of Medicaid patient days at a given facility.

104. Typically, each state requiring the submission of a Medicaid cost report also requires an authorized agent of the provider to expressly certify that the information and data on the cost report is true and correct. Individual Medicaid programs use the Medicaid patient data in the cost report to determine the reimbursement to which the facility is entitled. The facility receives a proportion of its costs equal to the proportion of Medicaid patients in the facility.

105. Where a provider submits the Medicare cost report with false or incorrect data or information to Medicaid, this necessarily causes the submission of false or incorrect data or information to the state Medicaid program, and false certification on the Medicare cost report necessarily causes a false certification to Medicaid as well. Where a provider submits a Medicare cost report containing the same false or incorrect information from the Medicare cost report, false statements and false claims for reimbursement are made to Medicaid.

106. Beaumont sought reimbursement from designated state Medicaid programs for the time period pertinent to this action. Each year since 1993, Beaumont submitted Hospital Cost Reports that falsely represented compliance with Medicare regulations and laws, including the Anti-Kickback Statute. These misrepresentations were material to the decision of the Government to pay for

services. CMS relied upon the certifications of Beaumont in paying for their services. In light of the foregoing, each CMS Form UB-92/UB-82 submitted by Beaumont under Medicaid was a false claim.

107. In addition to the hospital fees billed by hospitals, physicians also bill for their services provided to Medicaid patients. Physicians and physician groups submit form CMS-1500 for this purpose. The CMS-1500 claim form requires the physician to certify that the physician “understand(s) that payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal or State laws.”

108. By submitting CMS-1500 forms, physicians and physician groups certify that they are eligible for participation in the Medicaid program, and that they have complied with all applicable regulations and laws governing the program, including the Anti-Kickback Statute.

109. Since its inception, Academic Heart has submitted CMS-1500 forms for its Medicare patients even though it knew that it had not complied with applicable regulations and laws governing Medicare because it has violated the Anti-Kickback Statute. Academic Heart has been paid for these false claims. Academic Heart’s misrepresentations were material to the decision of the Government to pay for the services.

110. At all times relevant to this complaint, Beaumont was enrolled in, and sought reimbursement from, the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), now known as TRICARE Management Activity/CHAMPUS (“TRICARE/CHAMPUS”). TRICARE/CHAMPUS is a federally-funded program that provides medical benefits, including hospital services to (a) the spouses and unmarried children of (1) active duty and retired service members, and (2) reservists who were ordered to active duty for thirty days or longer (b) the unmarried spouses and children of deceased service members; and (c) retirees. Hospital services at non-military facilities are sometimes provided for active duty members of the armed forces as well. 10 U.S.C. § 1971-1104; 32 C.F.R. § 199.4(a).

111. In addition to individual patient costs, providers are required to submit a TRICARE/CHAMPUS form, “Requests for reimbursement of CHAMPUS Capital and Direct Medical Education Costs,” (“Requests for Reimbursement”) in which the provider sets forth its number of TRICARE/CHAMPUS patient days and financial information which relates to these two cost areas and which is derived from the facility’s Medicare cost report. This Request for Reimbursement requires that the provider expressly certify that the information contained therein is “accurate and based upon the hospital’s Medicare cost report”.

112. Upon receipt of a hospital's Request for Reimbursement and its financial data, TRICARE/CHAMPUS or its FI applies a formula for reimbursement wherein the hospital receives a percentage of its capital and medical education costs equal to the percentage of TRICARE/CHAMPUS patients in the facility. Beaumont submitted Requests for Reimbursements to TRICARE/CHAMPUS that were based on its Medicare cost reports.

113. Whenever Defendants' Medicare cost reports contained falsely inflated or incorrect data or information from which Defendant derived their Requests for Reimbursement submitted to TRICARE/CHAMPUS, those Requests for Reimbursement were also false.

114. Whenever Defendants' Requests for Reimbursement were false due to falsity in their Medicare cost reports, Defendants falsely certified that the information contained in their Requests for Reimbursement was "accurate and based upon the hospital's Medicare cost report" (emphasis added).

115. Beaumont sought reimbursement from designated state Medicaid program for the time period pertinent to this Complaint.

116. Each year, Beaumont submitted Hospital Cost Reports that falsely represented compliance with Medicare regulations and laws, including the Anti-Kickback Statute.

117. In addition to the hospital fees billed by hospitals, physicians also bill for their services provided to TRICARE/CHAMPUS patients. Physicians and physician groups submit form CMS-1500 for this purpose. The CMS-1500 claim form requires the physician to certify that the physician “understand(s) that payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal or State laws.”

118. By submitting CMS-1500 forms, physicians and physician groups certify that they are eligible for participation in TRICARE/CHAMPUS program, and that they have complied with all applicable regulations and laws governing the program, including the Anti-Kickback Statute.

119. Most **medical research** conducted in the U.S. is funded either by the federal government, primarily via the National Institutes of Health (“NIH”) or by private drug and device manufacturers who sponsor pre-approval clinical trials for FDA-regulated drugs and medical devices.

120. Both individuals and institutions that conduct research (whether federally or privately funded) and FDA-regulated drugs and device manufacturers who sponsor research face potential liability under the health care fraud laws for a wide array of research-related activities.

121. The process of applying for and receiving federal research funds is analogous to federal reimbursement for patient care. Applicants for NIH grants, for example, must submit an application, in which they describe their proposed research and budget and commit to abide by federal regulations that cover such subjects as research misconduct, conflict of interest, protection of human subjects, and various forms of discrimination. Specifically, Department of Health and Human Services, Public Health Service, Grant Application (PHS 398), Form II, as well as the NIH Application for Continuation Grant (PHS 2590) both contain such assurances.

122. Successful applicants accept grants subject to specific terms and conditions each time they draw down grant funds. Relevant terms and conditions include the obligation to comply with grant program legislation, program regulations, and the NIH Grants Policy Statement.

123. Research institutions generally receive funds on an outgoing basis through the NIH's Payment Management System, and costs and receipts are reconciled annually through Financial Status Reports (Standard Form 269).

124. When a project concludes, researchers are required to submit final Financial Status Reports as well as Final Invention Statements in which they must identify all inventions "conceived or first reduced to practice" during the course of the grant on the Final Invention Statement and Certification (HHS 568) and file

Certificates of Facilities and Administration (“F&A” costs), which describe the manner in which they have identified indirect costs and certify that all such costs are allowable in accordance with federal guidelines. The principals of determining cost applicable to grants, contracts, and agreements with educational institutions, as well as the required certifications relevant thereto, are set forth in Office of Management and Budget Circular A-21.

125. In addition, research institutions must file annual reports on possible research misconduct, certifying that they have established appropriate policies for responding to allegations of research misconduct and describing any allegations of misconduct. Each of these various reports requires some form of “certification” by either the research institution or the Principal Investigator (“PI”) as to the truth and accuracy of representations.

126. Some of these certifications are as follows:

Grant Application (PHS 398) and Application for Continuation Grant (PHS 2590):

**PI:** I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.

**Applicant Organization:** I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Service terms and conditions if a grant is awarded as a result of this application. I am aware that any false,

fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

Federal Cash Transactions Report (PMS 272):

I certify to the best of my knowledge and belief that this report is true in all respects and that all disbursements have been made for the purpose and conditions of the grant or agreement.

Financial Status Reports:

I certify to the best of my knowledge and belief that this report is correct and complete and that all outlays and unliquidated obligations are for the purpose set forth in the award documents.

Certificate of F&A Costs:

This is to certify that to the best of my knowledge and belief (1) I have reviewed the F&A cost proposal submitted herewith; (2) All costs included in this proposal...the establish billing of final F&A costs rates...are allowable in accordance with the requirements of the Federal agreement(s) to which they apply and with cost principles applicable to those agreements. (3) This proposal does not include any costs which are unallowable under applicable cost principles such as (without limitations): advertising and public relations costs, contributions and donations, entertainment costs, fines and penalties, lobbying costs, and defense of fraud proceedings; and (4) All costs included in this proposal are properly allocable to Federal agreements on the basis of a beneficial or causal relationship between the expenses incurred and the agreements to which they are allocated in accordance with applicable requirements. I declare under penalty of perjury that the foregoing is true and correct.

Final Invention Statement (HHS 568):

We hereby certify that, to the best of our knowledge and belief, all inventions are listed below which were conceived and/or first actually reduced to practice during the course of work in the above- referenced DHHS grant or award for the period.

127. Federally funded research involving human subjects is governed by several specific and highly technical regulations. *See* 45 C.F.R. Part 46; 21 C.F.R. Part 50.

128. Among these regulations is the requirement that each research institution have an Institutional Review Board (“IRB”), with responsibility for approving and monitoring all human experimentation. 45 C.F.R. §§ 46.107 to 46.115; 21 C.F.R. Part 56.

129. Beaumont’s IRB is known as the Human Investigations Committee (“HIC”).

130. The regulations also establish basic standards for “informed consent.” *See* 45 C.F.R. §§ 46.116 to 46.117; 21 C.F.R. §§ 50.20 to 50.27.

131. To be eligible to conduct research on humans, research institutions must provide written “assurances” to HHS that they will comply with these rules. 45 C.F.R. § 46.103. There are several forms of “assurance,” the most common of which is the Multiple Project Assurance, which provides that: “The officials signing below assure that any research activity conducted, supported, or otherwise subject to DHHS or other Federal departments or agencies that are authorized to rely on this Assurance...will be reviewed and approved by the appropriate IRB(s) in accordance with the requirements of all applicable subparts of Part 46, Title 45

of the Code of Federal Regulations, with this Assurance and stipulations of the IRB(s).”

132. Before September 2000, Medicare’s “Research Costs Regulation” stated that Medicare did not cover medical services provided solely as a result of a patient’s participation in a research protocol, but further stated that the costs of “unusual patient care” were reimbursable where research was conducted in connection with, and as a part of, the care of patients. 42 C.F.R. § 413.90(b)(2).

133. The Medicare Carriers Manual (“MCM”) took a more restrictive view, stating that services “related to and required as a result of services which are not covered under Medicare” are not themselves covered services. Medicare Carriers Manual, Part 3, § 2300.1(A). Some carriers and intermediaries, in turn, interpreted this instruction to prohibit any reimbursement for services related to uncovered services, such as research, regardless of the independent medical necessity of the otherwise covered services. Under these rules, these providers were required to identify services (such as laboratory tests, procedures, and physician services) that were provided to patients solely because the patients were involved in the research study, and their billing systems had to be configured to exclude such charges from Medicare billing.

134. In June of 2000, President Clinton directed the Secretary of Health and Human Services to “explicitly authorize [Medicare] payment for routine

patient care costs...and costs due to medical complications associated with participation in clinical trials.” President’s Memorandum to the Secretary of Health and Human Services, Increasing Participation of Medicare Beneficiaries in Clinical Trials” (June 7, 2000).

135. Soon thereafter, HCFA issued a proposed National Coverage Determination, which was finalized in September 2000. A copy of the Health Care Financing Administration’s “Final National Coverage Determination” can be viewed at [www.cms.gov/manuals/downloads/Pub06\\_Part\\_35.pdf](http://www.cms.gov/manuals/downloads/Pub06_Part_35.pdf). The National Coverage Determination (“NCD”) (1) defines the routine costs of clinical trials and (2) identifies the clinical trials for which payment for routine costs should be made.

136. For routine costs of research participants in a clinical trial to fall within the NCD, the clinical trial must (1) evaluate an item or service that falls within a Medicare benefit category and is not excluded from coverage by statute; (2) not be designed to test general subjects such as toxicity or basic disease biology; and (3) if for the purpose of therapeutic interventions, enroll patients with diagnosed disease rather than healthy volunteers.

137. Under the NCD, routine costs in clinical trials include: (1) items and services typically provided absent a clinical trial; (2) items or services required solely for the provision of the investigational item or service, the clinically appropriate monitoring of its effects, or the prevention of complications; and (3)

items or services needed for reasonable and necessary care arising from the provision of an investigational item or service – in particular, for the diagnosis or treatment of complications. Three categories of costs still are not reimbursable by the Medicare program: (1) the investigational item or service itself; (2) items or services provided solely to satisfy data collection needs (protocol-induced cost); and (3) items and services provided *gratis* by the trial sponsor.

138. The OIG has specifically addressed kickbacks in connection with research studies on a number of occasions. In a Special Fraud Alert issued in 1994, it identified several suspect “marketing” activities by manufacturers, including a “research grant” program in which physicians were given substantial payments for *de minimis* recordkeeping tasks. See Department of Health and Human Services, Office of Inspector General, “Special Fraud Alert” (Dec. 19, 1994).

139. Similarly, in revising the Space and Equipment Rental and Personal Services safe harbors in 1999 to require that safe harbored arrangements serve “commercially reasonable business purposes,” the OIG specifically noted that “[c]ost sharing or risk sharing arrangements, joint research initiatives, and data collection arrangements may qualify as commercially reasonable business purposes in many circumstances. However, we are aware of abusive arrangements involving contracts with referral sources for data collection services or research projects where the data to be collected or the research to be performed have no

value to the entity paying for them and are merely pretext for payments for referrals. Such arrangements do not comply with the safe harbor and are highly suspect under the anti-kickback statute. 64 Fed. Reg. 65,518-63,526 (Nov. 19, 1999).”

140. The Association of American Medical Colleges (“AMC”) issued several principles for creating institutional policies regarding financial interests in research conducted by a facility. Association of American Medical Colleges, Task Force on Financial Conflicts of Interest in Clinical Research, “Protecting Subjects, Preserving Trust, Promoting Progress-Policy and Guidelines for the Oversight of an Individual Financial Interests in Human Subjects Research,” (Dec. 2001).

141. The AMC suggested that policies “should establish the rebuttable presumption that an individual who holds a significant financial interest in research involving human subjects may not conduct such research... whether the research is funded by a public agency, a non profit entity, or a commercial sponsor, and wherever the research may be carried out.”

142. The AMC further notes that “[w]hen the financial interest is directly related to the research and may be substantially affected by it...the risk is greatest and the bar must be high; however, even direct and potentially lucrative financial interest may be justified in some circumstances.” If such a person is committed to conduct the research by the oversight committee of the facility, the research must

only be conducted “subject to conditions that ensure effective management of the conflict and credible oversight of the research.” *Id.* at 7-8.

143. The AMC further stated that institutional policies should require full prior reporting of each covered individual’s significant financial interests that would reasonably appear to be affected by the individual’s research, updated reporting of any relevant change in financial circumstances, and review of any significant financial interests in a research project by the oversight committee prior to final IRB approval of the research. Accordingly, “[i]nstitutional policies governing financial interests in human subjects research should be comprehensive, unambiguous, well-publicized, consistently applied, and enforced through effective sanctions.”

144. Finally, when an institution believes financial interests in human subjects research are justified by compelling circumstances, the situation must be managed “through rigorous, effective, and disinterested monitoring undertaken by individuals with no financial or professional ties to the research or direct reporting relationships to the researchers...In some circumstances, monitoring boards might be composed wholly of institutional representatives; however, when the institutional itself holds a financial interest in the research, disinterested monitoring might require the participation of individuals from outside the institution.”

145. A report from the OIG issued in January 2008 indicated that the NIH must improve its oversight of potential financial conflicts of interest at universities and other institutes that receive NIH grants. Department of Health and Human Services, Office of Inspector General, “National Institute of Health: Conflict of Interest in Extramural Research,” OEI-03-06-00460 (Jan. 2008).

146. The OIG offered three recommendations: (1) increase oversight of grantee institutions to ensure their compliance with federal financial conflict of interest regulations; (2) require grantee institutions to provide details regarding the nature of financial conflicts of interest and how they are managed, reduced, or eliminated; and (3) require institutes to forward to the NIH Office of Extramural Research (“OER”) all financial conflict-of-interest reports that they receive from grantee institutions, information from which is to be maintained in OER’s conflict of interest database.

147. Similarly, the Senate Finance Committee in 2008 conducted an investigation and uncovered “several instances where grant-funded doctors also have taken money from pharmaceutical companies and not reported it to their institutions.” *See* “NIH Improvement Needed on Managing Conflicts of Interest for Grantees, OIG says,” 12 Health Care Fraud Rep. (BNA) 3:118 (Jan. 30, 2008). *See also*, “Pennsylvania Medical Center Regulates Providers’ Contacts with Rx, Device Makers,” 12 Health Care Fraud Rep. (BNA) 5:185 (Feb. 27, 2008).

148. In the last few years several prestigious institutions, clinics, and universities have faced multi-million dollar fines for failing to document actual percent effort spent on grants, including a \$7.6 million settlement with Yale University for inappropriate cost transfers and salaries, a \$6.5 million settlement with the Mayo Clinic for mischarging research time to federal grants; an \$11.5 million settlement with Florida International for incomplete documentation, improper billing and Time & Effort reporting; a \$2.4 million settlement with Harvard for billing the government for salaries and expenses unrelated to federal grant; and a \$35 million settlement with the University of Washington for Medicare and Medicaid overbilling. Both Johns Hopkins University and Northwestern also received multimillion dollar fines for faculty T&E reports that were overstated or misrepresented.

## **FACTUAL ALLEGATIONS**

### **Illegal Incentives**

149. Ultimately, all of the fraud Relator has waded through at Beaumont comes down to Beaumont's efforts to sufficiently reward physicians for affiliating with Beaumont that they will remain loyal and provide referrals to the hospital. In this respect, all of the fraud is at least motivated by a desire to provide kickbacks to doctors, regardless of the legality of the various arrangements. Details of some of the many schemes are described below.

Illegal Incentives for Academic Heart & Vascular PLLC

150. Chief among Beaumont's cardiology groups, Academic Heart & Vascular PLLC ("Academic Heart"), consists of nine cardiologists who are salaried by Beaumont as full time employees (1.0 FTEs).

151. However, despite supposedly being full time salaried employees, these doctors also are allowed to maintain a private practice and keep remuneration from that private practice.

152. Academic Heart has its private offices on the grounds at Beaumont, pursuant to a highly confidential office rental agreement that upon information and belief requires them to pay less than FMV for the prime office space.

153. Thus, the Cardiologists receive (1) full time salaries from Beaumont, with the top four being paid well above any other Beaumont physicians; (2) all of the income from their private practice; and (3) office rental advantages for their private practice/Beaumont positions.

154. The 2009 salaries (which are 10% reduced from the past year) for the "big four" Academic Heart cardiologists are listed below:

|                          |           |
|--------------------------|-----------|
| David Haines, M.D.       | \$753,067 |
| Cindy L. Grines, M.D.    | \$726,499 |
| James A. Goldstein, M.D. | \$702,294 |
| Robert D. Safian, M.D.   | \$702,294 |

155. This is well above typical salaries for cardiologists, according to any recognized benchmark.

156. Moreover, whereas the salaries of other physicians are covered by the billables collected for their clinical work, in the case of Academic Heart, the Cardiologists are paid these exorbitant salaries and are permitted to keep monies collected through clinical efforts via Academic Heart. Thus, these enormous salaries are provided to the Cardiologists as a pure kickback for conducting their practice at Beaumont.

157. This illegal arrangement is openly discussed at Beaumont. Relator has had conversations regarding the full time salaries (and their inappropriate nature) with Tom Thompson, the former Vice President for Beaumont Professional Services (“BPS”), who stated that the compensation arrangement was written into the contracts.

158. Relator has had numerous other conversations with John Meloeny (BPS Financial Director); Charles Shanley, M.D. (Senior VP and now Associate CMO in charge of physician salaries and contracts through the new CARTS methodology); Ananias Diokno, M.D. (Chief Medical Officer to whom these cardiologists report); Karen Turner (Tom Thompson’s successor, who soon left because of the illegalities in physician contracts); and many physicians who have been at Beaumont for several decades and who are fully aware of the arrangement.

159. In a meeting with his direct supervisor, CMO Ananias Diokno, M.D., on February 15, 2010, Relator asked Diokno point blank about the cardiologists being paid exorbitant salaries by Beaumont yet being allowed to keep revenue from their private practice at Academic Heart. Diokno admitted that the compensation arrangement is a problem, which goes back to the arrangements made with William O'Neill, M.D., and stated his hope that the CARTS methodology would straighten it out, and then quickly changed the subject.

160. A highly respected Internal Medicine physician, Sandor Shoichet, M.D., also discussed this situation with Relator on March 15, 2010 at the Royal Oak physician's staff meeting.

161. As is further discussed below, several of these same Cardiologists also have been involved in using clinical nurses for research clinical trials without reporting their involvement to the Research Institute, thereby having the nurses' salaries roll up to the Medicare Cost Report.

162. These same Cardiologists also charged non standard of care research procedures to the hospital's clinical budget rather than to the proper research budgets.

163. When such charges are billed to the hospital (who then passes the cost to the government), it leaves large surpluses in the research budgets, which historically remained in the study's operating account to be treated as a purely

discretionary “slush fund” for the researchers. Over time, the doctors have come to view these “surpluses” as their rightful property, to dispose of as they wish.

164. Former Research Institute Administrative Director Veronica Decker and Relator have been vilified repeatedly by the cardiology researchers for trying to stop these practices that led to inappropriate “surpluses” from their research studies.

165. Beaumont Comptroller Bob Courtoise was laid off in part because of his attempts to correct some of these practices, and Relator and others at the Research Institute are regularly under attack for frustrating the old system.

166. Dr. Grines has openly stated that she now carries out research separate from Beaumont because the hospital would not “incentivize” her by paying her extra to do research. Grines stated she would continue to accept remuneration and funded research, without declaring it to Beaumont and apparently with no IRB supervision or monitoring.

167. Similarly, Dr. Haines openly stated in the CMO Leadership group on February 17, 2010, that he strongly opposed the Beaumont requirement in the new Conflict of Interest Policy which requires that he and his Academic Heart colleagues are no longer permitted to accept consulting fees for representing companies that sell cardiac devices. Haines stated flatly that if this policy was not

changed, they would continue to do the consulting, but not report the compensation to Beaumont.

168. There is ample evidence that such practices already occur. For example, Dr. James Goldstein owns shares in Eco Cath Lab Systems, Inc. (ECLS), a company that is developing his shielding device to protect patients and physicians from radiation in the cath lab. Without permission and without following proper IRB/review procedures, Goldstein used Beaumont's cath lab and personnel to test his own invention. He did so in the face of RI opposition and outright directions to cease. Moreover, Goldstein was allowed to own the resulting IP in his own name, despite his full time employment status with Beaumont.

169. Similarly, press releases brought to the attention of Beaumont that Dr. Cindy Grines was part of the "Spirit IV" trial for Abbott when the Research Institute had neither approved nor supervised such trial. Apparently Grines used Beaumont's name and performed the trial for Abbott in her private practice, for whatever compensation was agreed to between them.

170. Dr. Grines retaliates against efforts to control her research practices by refusing to provide final reports for grants on which she is the Principal Investigator.

171. Incredibly, Dr. Haines openly suggested to Relator that Grines simply needed to be bribed to submit such reports:

As I mentioned to you in our meeting, Dr. Grines is disenchanted/disenfranchised presently. The final reports that are due on her studies that will result in ~ \$200K are entirely dependent upon her effort. I would not be surprised if she never did these reports. I have a proposal. I would like to suggest that you communicate to her the following. Upon receipt of the final reports, the study sponsors will remit those funds, and those funds become her discretionary funds for future research. Now I know that there are all sorts of compliance issues to work through with this plan, and that those funds cannot actually reside in her account. But couldn't you keep a running virtual account for her that is equivalent to that amount? When she needed money, she would just debit RI, and that would come off your bottom line.

I think that this is a win-win. If you don't make this kind of gesture, Beaumont will probably never see that money. If you go forward with my proposal, it will be a tremendous act of reconciliation from you to Dr. Grines, the money will be in your hands, and Dr. Grines may never spend down her virtual account. If she does spend it down, then you have no less than you would have had otherwise, but we will have an engaged researcher with new productivity.

What do you think?

172. It is also well documented that Dr. Grines has openly taken hospital property such as furniture and computers to keep at her home.

173. Finally, Relator has been informed that the Northpoint Cardiology group (as distinct from the Academic Heart group) has an illegal arrangement with Providence Hospital. Even though these physicians are supposedly full time Beaumont employees, they have established a joint venture with a cath lab at Providence, with the physicians as "shareholders", to provide extra income from

the shares from referrals that the Northpoint cardiologists send to Providence. There are 11 cardiologists in this group.

Illegal Incentives For Beaumont Oncology Network (“BON”)

174. Apparently looking towards the cardiology model to achieve extra compensation, the Beaumont oncologists (radiation oncologists and medical oncologists) threatened to walk out of Beaumont and set up their oncology practice elsewhere if they did not also get a “special deal.”

175. As a result, the Beaumont Oncology Network (“BON”) was formed by Dr. Frank Vicini, Dr. Alvaro Martinez, and a group of private practitioners that includes Jeff Margolis, M.D., the current head of BON.

176. The agreement between BON and Beaumont contains a host of incentives and bonuses for “performance standards,” which cost Beaumont many millions of dollars per year.

177. Some of the incentives include payment for enrolling patients into research clinical trials, including those in the NIH-funded Community Clinical Oncology Program (“CCOP”), something that the AAMC and the AMA both consider unethical.

178. Relator personally reviewed a draft of the contract, which included such incentives; however, no physician with whom Relator has spoken, including Dr. Shanley, Associate CMO and the Executive Vice President responsible for

putting the CARTS program in place, has actually seen the final signed BON agreement. It has been kept completely secret.

179. BON appears to be an out-and-out kickback scheme, created in order to keep the very lucrative oncology dollars flowing to Beaumont. It is well known that the agreement boils down to “points for enrollment, and payment for points.” Essentially, it calls for BON physicians to earn “points” for educational contributions and enrollment of patients in clinical trials. These points then are translated into additional incentive payments at the end of the period of accumulation.

180. Other groups protested immediately and loudly about this arrangement, labeling it a kickback. In response, the BON leadership argued that BON was established as a “service agreement” as distinct from a “practice agreement.”

181. However, even some of the oncologists do not agree and feel threatened by this joint venture, because they were told that they must join BON if they wish to practice Oncology at Beaumont.

182. In fact, David Decker, M.D., the most productive research oncologist and Director of the NIH-funded CCOP, resigned in large part because he did not want to be party to what he considered an illegal kickback scheme.

183. The research nurse manager for all of oncology, Joyce Tull, stated to Relator on March 22, 2010 that Beaumont's administration signed the agreement under considerable duress, because both the radiation oncologists and the medical oncologists were threatening to leave Beaumont immediately if the BON contract was not signed.

184. Relator also discussed the BON agreement with Dr. Charles Shanley in that same March 22, 2010 meeting. Shanley, who is charged with implementing CARTS, admitted that BON was exempted from that process and thus will not be "fixed" by the CARTS model. He referred to it as a "separate, special deal."

185. Despite the fact that he is the Executive Vice President and Associate CMO over physician compensation, Shanley told Relator that he was not brought into the negotiations, was not told the final details of the contract or incentives, and was not to be involved with the management of the BON venture.

186. Now many other groups of physicians in other disciplines are clamoring for similar "joint ventures" to "incentivize" them in the same way BON incentivizes the oncologists.

187. Radiation Oncology also has made joint venture arrangements with another system, Botsford Hospital.

188. Some of Beaumont's full time employees (notably Alvaro Martinez, M.D., Chief of Radiation Oncology) are now listed as Botsford Radiation Oncologists.

Other Illegal Incentives

189. There are many other physicians who have been described as having "special deals" with their contracts that are highly questionable. Some of this information comes from Karen Turner and Tom Thompson, and some of it comes from physicians such as Sandor Shoichet, M.D., who described Ralph Margulis, M.D., from Ob/Gyn as having one of the most blatant special deals, ongoing for over a decade.

190. Another example is that of Kenneth Peters, M.D. Prior to becoming Chair of Urology in 2008, Peters was the Director of Urology Research, a job which was supposed to require 40% of his T&E and cover 40% of his compensation.

191. Separate and distinct from those activities (whatever they might be – recall that there are no job descriptions for Medical Directors at Beaumont), Peters also was personally overseeing several commercial studies that involved clinical trials, each of which normally require at least 5% effort.

192. At the same time, he was receiving NIH compensation for 35% for participation in two NIH grants.

193. Yet somehow, Peters also managed to maintain a full time private office practice of urology.

194. Relator looked at the breakdown of Peter's supposed time and effort and objected to providing 40% compensation from the research budget for what appeared to him to be a purely honorific title. There ensued a heated debate with Dr. Diokno, then Chair of Urology. Relator explained that such a reward for loyalty was inappropriate because the federal government did not allow a percent effort greater than 100%. Diokno argued that Dr. Peters worked long hours. Relator pointed out that long hours are irrelevant for reporting *percent* efforts and commitments.

195. Notably, Diokno himself, now in the full time position of Chief Medical Officer, still charges 23.5% of his time to NIH research – a statistic that has caused ongoing concern in the RI.

196. Dr. Peters is just one of many “Medical Directors” and other leadership positions at Beaumont that pay a partial salary for which there are no job descriptions, no expectations, no performance standards, no metrics, and no recorded evidence of any activities in exchange for the payment. Since Relator does not have immediate access to the BPS contracts, he only encounters full evidence of these situations as they arise in the research arena.

197. Another example is that of Stuart Gordon, M.D., a gastroenterologist who practiced at Beaumont until approximately 2005. Gordon carried out research studies and also had a private practice in gastroenterology. Dr. Gordon claimed to be fully engaged in research at his office facility at Beaumont and (prior to Relator's arrival) convinced the Research Foundation and the Research Institute to pay 100% of the cost of his office space.

198. On his Medicare Time & Effort reports, Gordon claimed 100% research activity. Relator noticed that this was entirely inconsistent with the number of patients actually enrolled in the research studies.

199. Moreover, several individuals who were known by employees of the Research Institute, including Jack DeChellis's mother, saw Dr. Gordon as a private physician in the same facility for which Beaumont was paying 100% of the rent.

200. It became evident from these episodes that Dr. Gordon was billing third parties (Medicare or insurance) for these patient visits.

201. Jack DeChellis and Veronica Decker (before Relator arrived) brought this situation to the attention of Beaumont, but no one wanted to explore this further because investigation would have required getting Dr. Gordon's private office records, and no one wanted to put the significant referrals that he brought to Beaumont at risk.

202. Ultimately, Dr. Gordon left Beaumont for private practice, and sued Beaumont for “fees” that he claimed were owed to him in association with his research. Gordon lost the case, but during the discovery process, the RI uncovered both proof that Gordon had been seeing private patients in the office space provided 100% by Beaumont for research, as well as evidence that Gordon had engaged in theft of some Beaumont property.

203. Beaumont did not want the bad publicity of trying to countersue and make claims for fraud against Dr. Gordon, so the entire event was swept under the rug.

204. As discussed above, FTI consultants noted an array of “sweetheart deals,” including 56 medical directorships which had virtually no job descriptions, no performance standards or expectations, no metrics, and no evaluations.

205. FTI also noted that Beaumont has 318 “Mid-level Providers” (Nurse Practitioners and Physician Assistants), accounting for 222 Full Time Employees (64 providers who worked for physicians and the remainder employed directly by hospital units). These mid-level providers billed at an incredibly low productivity of 19% of median RVUs as measured by the MGMA benchmarks. In other words, these providers are producing less than 20% of the expected median Relative Value Units of mid-level providers at benchmarked institutions. Internal productivity standards do not exist for this group.

206. To Relator's surprise and dismay, several physicians who attended the September 14, 2009 meeting to review FTI findings actually tried to assure the consultants that the situation was explainable. They argued that many of these Mid-level Providers, paid for by Beaumont resources, were working much harder than was reflected because they were actually working in the private practices, helping the private physicians. The FTI consultants described this revelation in the meeting as a serious "OIG issue."

207. Finally, Relator recently found out that there is another problematic joint venture in the Ambulatory Care Division. Beaumont has "leased out" one of its financial analysts to this joint venture. That financial person then arranged for the contracting services of a private company in which he has ownership (and receives profit) to carry out some of the tasks, thereby making money off of his own company contacts through a blatant conflict of interest.

208. As usual, Beaumont has "let it go" since it "incentivizes" the important ambulatory care division to provide the hospital with referrals.

### **Cost Reporting Fraud**

209. When hospitals compile their annual Cost Reports, they provide salaries of clinical personnel who have billed their time through the hospital and request reimbursement.

210. As discussed above, it is expected and appropriate that personnel who are not 100% devoted to clinical activities will not bill 100% of their salary/time to the clinical budget (and thus to Medicare). Instead, staff who devote time to research activities are supposed to carve out their research T&E from the hospital's Cost Report.

211. Prior to 2005, Beaumont made no effort at all to segregate research T&E. In fact, the form used by physicians to report their Medicare billable T&E did not even have a line item for research. As a consequence, all research-based time was reported as a clinical activity and "rolled up" to the Medicare Cost Report.

212. When Relator asked Tom Thompson (head of Beaumont Physicians Services) why this practice was permitted, Thompson replied that he did not see the necessity of accounting for research time and effort.

213. Relator and Jack DeChellis estimate that this lack of knowledge resulted in transferring approximately \$2 million annually of physician research T&E to the clinical category.

214. Beginning in the 2005 Cost Report, Beaumont made an attempt to separate clinical T&E from research T&E.

215. However, this effort is limited to having physicians self report a "ballpark" of how much of their time is spent on research activities. Not only are

there obvious incentives to under-report research time (so that salary is rolled up to Cost Reports rather than deducted from the department's own research budgets), there is ample evidence that this underreporting is actually happening.

216. In a physician compensation meeting on March 22, 2010, Jedd Roe, M.D., Chief of Emergency Medicine at Royal Oak, stated openly that the physicians under his direction only report Research T&E for NIH-funded projects, where an extramural salary was paid. They systemically refuse to report research activities related to internally-funded research or investigator-initiated projects. Such research efforts are instead recorded as standard clinical activity, thus underreporting research and over-reporting clinical efforts.

217. Another egregious example is that of Peter McCullough, M.D., Chief of Nutrition and Preventive Medicine. McCullough has a robust research program with many studies, multiple peer-reviewed publications every year, and extensive interactions with commercial sponsors and at scientific meetings. Despite all of this activity, McCullough reported a mere 27.74% research effort in 2005, and an even less believable 1.29% research effort for 2009.

218. The actual number is probably closer to 50% of McCullough's total T&E. As a result, McCullough's clinical productivity appears to be low for the large amount of clinical time reported on the Medicare T&E reports.

219. McCullough has been very active in resisting any effort by the RI or Relator to curtail his activities, even going so far as to inform research sponsors that he was “removing” Relator Felten and the RI from his projects and requesting that a new contract be sent, a position he was forced to retract by CMO Diokno.

220. Relator has personal knowledge of this ongoing Cost Reporting fraud through his work as Medical Director of the Research Institute. For example, in 2006, he noted that:

[Radiation Oncology] still steadfastly refuses to properly account for their research nurses, despite having been told to do so repeatedly. They still have 01 [clinical division] nurses carrying out 08 [research division] research protocols (listed as key personnel on HIC-approved studies), and then presumably reporting their activities as entirely clinical on the Medicare time and effort reports. This, of course, is entirely illegal, and puts [Beaumont] in potential jeopardy with the OIG. If these nurses come over to the Rad Onc 08 research budget, as is proper, then this will result in an even greater deficit (or subsidy) for Rad Onc.”

221. In 2007, with the help of then-Comptroller Bob Courtoise, the RI staff was able to access the clinical time reports on a limited basis from Beaumont’s 01 clinical division and compare those records with personnel’s participation in both clinical and research activities.

222. The resulting review showed many nurses, especially in Cardiology and Radiation Oncology, were working on research protocols but reporting 100%

of their time as “clinical” and none of their time as “research.” In all, the report shows thirteen such nurses at a minimum.

223. The RI took those results to the Chiefs and told them to clean up the misreporting. Relator was assured by the Chiefs that this had been handled. The RI then tried to make the salary adjustments to recapture those efforts back into research and get them off the clinical time reports. Relator believed the issue had been successfully dealt with at that point.

224. However, on February 17, 2010, in a meeting called by Val Gokenbach, R.N., (Vice President, Nursing) and Scott Flowerday (Corporate Finance, Chief Signatory of the Medicare Cost Report), Relator was informed that radiation oncology’s clinical productivity was “abysmal” and that their group required significantly more employees for radiation oncology clinical treatment (RVUs) than their benchmarked institutions in the Southeast Michigan region. ‘

225. It then was revealed that the reason for both this poor productivity and for the apparent excess of Ph.D.-level physicists, nurses, and other personnel in radiation oncology is due to extensive research commitments. At this meeting, it appeared that at least fifty individuals were involved in this scheme. Yet these researchers were not reporting any of their activities to the Research Institute, were not filling out T&E reports, and were hiding their research activities as “clinical”, thus rolling up all of their time to the Medicare Cost Report.

226. Relator openly stated at this February 17, 2010 meeting that such actions constituted deliberate fraud. Although the Chief of Radiation Oncology, Dr. Alvarez, acknowledged at that time that the reporting was incorrect, he resists the change because it will force his research budget to absorb sizable salary amounts from these physicists and nurses.

227. Relator spoke with several people in Radiation Oncology to try to get to the bottom of how long this policy of hiding research activity on the clinical time reports has been going on. The answer is “forever” or at least for many, many years.

228. In addition, according to the oncology research nurse manager and some of the employees, the radiation oncology administrator, Hari Menon, told these clinical personnel working on research that they were “forbidden” to report their time to the Research Institute, and claimed that the direction came from “the highest level of authority.”

229. Relator asked Joanne Gondart and Joyce Tull to look further into this situation. On March 23, 2010, Relator received from them the list of personnel who have their time now reported as clinical for the Medicare Cost Report, but have involvement in one or more of the eighty ongoing radiation oncology research projects. That list includes: (1) thirty nurses, therapists, dosimetrists, and nuclear med technicians; (2) eight Ph.D. level physicists; (3) two non-physics

executives; (4) thirteen other employees or students/visiting fellows; and (5) eight employees from the Troy Beaumont campus. This level of activity apparently has been ongoing for many years.

230. Relator had a follow up conversation with Ms. Gokenbach on August 3, 2010, in which she reported that at least her clinical nurses who had been on the list of 50 personnel doing research in Radiation Oncology had finally had been removed from her budget.

231. Relator was informed by the oncology research nurse manager, Joyce Tull, and Jack DeChellis, on August 4, 2010, that Dr. Alvaro Martinez was attempting to move the salaries of some of the research physicists onto the CCOP budget, which is an NIH funded research program. Martinez wanted the change to be effective immediately, thereby offloading these salaries from his home account, which is funded primarily by the Elekta Royalties (see below).

232. This is a continuation of a pattern in Radiation Oncology of moving salaries of employees to NIH grants even though they are not carrying out the specific aims or functions of the NIH grant.

233. This gambit by Alvarez to move his research salaries onto NIH funding was confirmed on August 25, 2010, in a meeting between Relator, Gary Chmielewski, M.D., (Principal Investigator of CCOP), Joyce Tull, Jack DeChellis, and Mary Thill.

234. Tull confirmed that Alvarez is seeking to move Rad Onc physicists' salaries to the CCOP budget. She noted that there is no justification for such a move, because physicists would only be needed if the patients were receiving image-guided radiation therapy ("IMRT"). But any IMRT being provided is a choice for therapy that is being made clinically, not as part of research, because IMRT is not part of the CCOP protocols.

235. At that meeting, Relator was also informed by Joyce Tull that BON has been making ongoing demands for reports and clinical trials details, the provision of which is taking huge amounts of RI staff time. This is totally inappropriate, since BON is a private corporation and does not have the right to demand anything from Beaumont, a 501(c)(3), without paying for it. (Of course, Beaumont goes along with these demands because instead of cash, Beaumont is being paid in referrals.)

236. In addition, Joyce Tull shared that a plan for a new Phase 1 drug development program is being made by BON, so all of the financial information and reports that Beaumont is making at this time are in the same category. Tull believes that BON is using the clinical trials enrollment data inappropriately, and she believes that they are deliberately misrepresenting the data to make it look as if their BON members are enrolling more subjects in the clinical trials than they actually are.

237. They are motivated to misreport enrollment by the BON incentive structure, which Tull confirmed is still using the point system for enrollment, followed by payments for these enrollments.

### **Research Fraud**

#### **Overview**

238. When Relator joined Beaumont in October 2005, Veronica Decker, R.N., was the administrative director of the Research Institute and had been managing the RI while the search for a new Medical Director proceeded. She reported to Tom Thompson of BPS.

239. When Ms. Decker assumed the leadership role, she was appalled by the situation at the RI. She immediately started the process of attempting to control physician behavior and activities that were deemed to be inappropriate, in violation of regulations, or out and out illegal, which Relator's predecessors in the post of Medical Director of the Research Institute had apparently allowed or even encouraged.

240. For example, as alluded to previously, one very popular scheme was used to create a "surplus" budget for a physician-researcher's discretionary spending. In this scheme, the researcher first accepts research support from commercial vendors. The researcher then is supposed to bill the research study budget for all non standard-of-care procedures and for research salaries. Instead,

however, the researcher would bill private insurance or Medicare for these research activities, and roll up the salaries onto the hospital's Cost Reports. Money not used for such procedures then remained in the budget as "budget surpluses."

241. These supposedly surplus funds were accumulated into special accounts (slush funds), which were then used for whatever the investigator wanted, including unfunded research studies, travel, or in some cases even investigator fees that went into their own pockets.

242. Moreover, many private physicians were carrying out private research on private patients in their private offices, using funds, research nurses, and resources provided by Beaumont. This amounts to having the hospital, a 501(c)(3), providing resources to private physicians for their private practice research, thereby incentivizing them and keeping them loyal for their clinical referrals.

243. In addition, some private physicians (notably those in GI and ophthalmology) were using space paid for by the Beaumont Research Institute (or the Beaumont Foundation, from philanthropic funds), with the stated intention that this space was being used for Beaumont research.

244. Instead, the space was being used for private practice research, or even worse, for clinical (non-research) office visits for private patients, presumably being billed through Medicare or private insurance.

245. Prior to Relator's arrival, Beaumont knew all about these types of practices but had done nothing to stop them.

246. All of these practices increased the slush funds available to researchers at Beaumont.

247. Compounding the problem (literally), despite IRS regulations and Generally Accepted Accounting Principle requirements that any leftover research funds be swept into the corporate accounts at the end of each calendar year, such funds were instead allowed to remain available to the researchers from year to year.

248. When Veronica Decker determined the source of these funds, she froze the accounts, confiscated funds, and tried to stop the blatantly dishonest practices. For this, she was utterly vilified and was under vitriolic attack on an almost daily basis.

249. Under Decker's direction, Jack DeChellis instituted accounting practices to accurately account for all research expenses. Soon he, too, was under constant attack from the physicians, who wanted to continue with the slush funds and lack of accountability.

250. As described above, DeChellis insisted that physicians account for Research T&E on the Medicare T&E reports required of physicians. In making this change, DeChellis estimates that total physician time devoted to research,

previously rolled up to the Medicare Cost Reports, was at least \$2 million per year, and continues at that level and more.

251. Relator's arrival was met initially with substantial relief from the physicians, who expected him to "play ball" in the manner of his predecessors. When he arrived, he rapidly came under intense pressure by the physicians to "rein in Veronica Decker" even though she initially continued to report to Tom Thompson.

252. The physicians came to Relator in droves wanting him to return to the good old days where they could "get research done the way it used to occur" and to help them to "incentivize" their activities.

253. One physician, Peter LeWitt, M.D., told Relator that Relator should look into ways in which Relator himself could make money off of research studies. Relator responded that a properly budgeted research study, honestly run, would not make any money and would be lucky to break even. His response was, "If you are too stupid to be able to make money off of research, then you are too stupid to hold the position of Medical Director of the Research Institute."

254. Relator soon realized that Beaumont's culture was all about making money for the physicians and helping to keep them happy and loyal so that they would continue to refer patients to Beaumont.

255. Within a few weeks of starting work at Beaumont, Relator informed the Chief Medical Officer (then Ronald Irwin, M.D.) of the myriad of illegalities he had observed. When the physicians realized Relator would support Decker's reform measures, they turned on the two of them with what Relator describes as "a fury like I had never experienced in 30 years in academics."

256. The "big players" in research (William O'Neill (cardiology), Alvaro Martinez (radiation oncology), Frank Vicini (hematology/oncology), Ananias Diokno (urology), George Williams (ophthalmology), and Neil Goldstein (pathology, later dismissed for altering an outside lab report) wrote a vicious letter to Dr. Irwin on March 14, 2006 with a myriad of false and unsubstantiated allegations (all generalizations, no specifics), seeking to achieve the dismissal of Veronica Decker and Relator.

257. Dr. Irwin asked Relator to put together a request for the complaining doctors to give specific examples. Not one of the complaining physicians was able to respond. Dr. Irwin and Relator met with each individual in that group and made it clear that their past behavior, activities, and unrelenting attacks needed to end. Irwin clearly indicated his support for what Relator was doing.

258. This support, however, merely led to attacks on the Chief Medical Officer himself. By October of 2006, they succeeded in leading a coup, and Ananias Diokno, M.D. was appointed as Chief Medical Officer.

259. When Diokno assumed the leadership role, Relator fully expected to be fired. Instead, Diokno assumed an attitude of benign neglect as to the compliance issues, informing Relator that he was “looking into” the problems, setting up panels and “blue ribbon committees”, seeking a host of outside inputs, and slowly marginalizing Relator’s influence.

260. Dr. Diokno was supportive of many changes Relator made to enhance services, grant activities, and new research technologies at the RI, and seemed to come to understand, once he took on the role of CMO, that some of these compliance issues would eventually need to be addressed.

261. The departure of William O’Neill, M.D., as Chief of Cardiology further reduced the overt attacks, and Relator was then reassured that the issues about which he was concerned had been cleaned up. He had no choice but to believe that clean up had occurred, because for the most part, RI did not have access to the hospital records, rental information, BPS salary information, and other data necessary to substantiate these claims.

262. In this respect, the FTI report was a nightmare for Dr. Felten, proving that most of what he thought had been addressed was actually still going on.

#### Research “Slush Funds”

263. As described above, in cardiology, Cindy Grines, M.D., and others were using clinical personnel to carry out research and not reporting it as Research

T&E, thereby saving the cost of salaries from their research grants which they considered as surpluses to be moved into discretionary accounts for their own use. These problems appear to go back many years and have been hidden and covered up from the Research Institute.

264. George Williams, M.D., Chair of Ophthalmology as well as a private practitioner with Associated Retinal Consultants, had a variation of this scheme that he used for retinal research. On the surface, ARC appeared to be complying with government regulations. Williams and his ophthalmology colleagues carried out Beaumont studies through the RI and enrolled Beaumont patients. They also carried out ARC studies, in the ARC private offices, by private ophthalmologists, overseen by outside, non-Beaumont IRB human subject protection.

265. Unfortunately, Williams frequently comingled the two, using Beaumont RI employees (paid by the not-for-profit hospital) to carry out the research activities for private physicians in their private office practice, thus utilizing Beaumont funds for their own private practice benefit.

266. Relator's predecessor, Mark Zervos, M.D., supposedly knew about this, but apparently did nothing to stop it.

267. Indeed, Williams used Beaumont research dollars to support his ARC research activities as well, and had helped to set up a Beaumont Foundation Fund

(ROPARD) to channel not-for-profit donations into his private practice, ARC (see details below).

268. When Relator joined Beaumont in 2005, Dr. Williams was in the process of seeking a \$250,000 payment for architectural and remodeling fees for his private practice office using Beaumont Hospital research funds.

269. When Relator, Veronica Decker, and Jack DeChellis stopped this from occurring, Williams joined the effort to try to get both Decker and Relator fired for “obstructing his research.”

270. Peter LeWitt, M.D., a neurology researcher, had a different variation of this scheme. LeWitt had robust research support for studies relating to Parkinson’s disease, which involved both federal and commercial grants. With the support of previous RI Directors, LeWitt assigned himself 55% of the total research budget as “investigator fees.” He did so despite the fact that he himself had limited patient contact, choosing to have his research nurse handle almost all of the research interactions and data collection. These huge investigator fees (paid to him directly) resulted in his commercial studies running huge deficits. The RI then absorbed the deficit. By this mechanism, he enriched himself with 501(c)(3) funds.

271. When the RI shut down the scheme and banned LeWitt from doing research at Beaumont, he went to the top levels of the administration to try to reverse these actions.

272. In a face-to-face conversation, LeWitt told Relator that Relator “was costing him a sizable amount of his take home salary.”

273. Relator was brought into no fewer than seventeen meetings with various medical and hospital administrators to “justify” RI’s treatment (often called “mistreatment”) of Dr. LeWitt.

274. Ultimately, LeWitt left Beaumont and joined the Henry Ford Hospital system.

275. Notably, PriceWaterhouseCooper, which audited LeWitt’s research practices, also found LeWitt’s investigator fees totally unjustified.

276. In addition, a past Medical Director of the Research Institute had inappropriately approved rental of space for LeWitt’s research activities in Southfield at his private practice.

277. Moreover, Beaumont apparently paid several tens of thousands of dollars in legal fees to support LeWitt’s personal lawsuit against his former employer as another “perk” to keep him loyal to Beaumont, despite the fact that Beaumont had no stake in the lawsuit at all. Relator learned about this attorneys’ fee payment from Ron Irwin, M.D., then-CMO.

### Elekta Research Fraud

278. Elekta is a Swedish company and a world leader in image guided and stereotactic clinical solutions for radiosurgery and radiation therapy. Elekta was founded in 1972 by the late Lars Leksell, Professor of Neurosurgery at the Karolinska Institute in Stockholm, Sweden.

279. Today, Elekta solutions in oncology and neurosurgery are used in over 5,000 hospitals globally. Elekta employs around 2,500 employees globally. The corporate headquarters is located in Stockholm, Sweden, and the company is listed on the Nordic Exchange under the ticker EKTA.B.

280. Historically, Beaumont has had several research agreements with Elekta. The first research agreement was initiated in the early 2000s and ended at the close of 2004. Radiation Oncology used this Elekta research money to support a host of researchers, particularly physicists, and was moving aggressively to achieve its research goals.

281. The next Elekta research agreement was expected to commence immediately, in 2005, but got bogged down and was not signed until March 22, 2007. Relator signed this second Technology Research Agreement, which was for over \$1 million dollars, as Beaumont's Institutional Official.

282. Because of this delay in signing, a period of two full years or more went by for which there were no Elekta research funds. Di Yan, Ph.D., the director

of these projects and head physicist overseeing Cone Beam technology, was very unhappy, as he needed the support to pay project personnel.

283. Yan made it clear that he had no intention of slowing down the Elekta research projects. He had his entire research team continue full steam ahead.

284. As Vice President of Research, Relator asked Yan directly how he had funded this ongoing work. Yan replied that he had simply transferred as many of the personnel as possible onto NIH grants, noting that there was a “lot of flexibility” in NIH grants and how you spent them, and that NIH “did not care what you did with the money once you had the funding.”

285. Since that certainly did not correspond to Relator’s experience with the close scrutiny NIH grants typically received, he reacted very strongly. Yan then backtracked and said that he now recalled that this work had been supported by philanthropy or Beaumont funds.

286. In a later attempt to recover the 2005 and 2006 costs retroactively from Elekta, Yan put the total amount for those two years at \$968,625.

287. The RI team has tried to dig to the bottom of this issue, but because of the utter lack of records, lack of T&E reporting, the sheer number of studies (over 80), and shuffling of personnel back and forth from clinical categories to research categories, it has been virtually impossible to unravel.

288. What is apparent, however, is that Radiation Oncology continued to carry out the Elekta work (for a private, foreign, for-profit corporation), did not lay off any of the research personnel, and by the director's own admission covered close to \$1 million in research expenses from somewhere.

289. If the nearly \$1 million was from NIH grants, such misuse of funds is fraudulent and utterly inappropriate. If it was from Beaumont, then they were using funds from a not-for-profit to enrich a private, foreign business, or worse yet, were shifting costs from research to the Medicare Cost Report and letting the hospital pick up the extra personnel costs.

#### ROPARD Fund Fraud

290. As discussed above, Beaumont Hospitals has a longstanding association with a group of renowned private practice ophthalmologists who are internationally known for their work in Retinopathy of Prematurity ("ROP"). All of these physicians are full time practitioners in Associated Retinal Consultants ("ARC").

291. One of these physicians, George Williams, M.D., is listed as a Beaumont physician employee, and also receives a stipend from Beaumont for service as the Chair of Ophthalmology.

292. As also noted above, ARC carries out much research (especially ROP research) in their private practice. The Beaumont Ophthalmology program also

carries out research, which must go through the hospital and the HIC when it involves Beaumont patients, Beaumont facilities, or other Beaumont resources.

293. In the past, the RI had significant problems with ARC utilizing Beaumont resources to support ARC research in the private practice. Even though it was known by Beaumont leaders to violate the regulations about not-for-profits benefiting a private practice, the practice was tolerated by Beaumont prior to Relator's arrival because ARC provides significant and financially rewarding referrals to the hospital.

294. The ROPARD Fund was established in 1990 by Trese, Williams, and other physicians and individuals as an international eye research foundation. It was created as a 501(c)(3) fund through the Beaumont Foundation.

295. The ROPARD Fund's bylaws require an independent board of directors, functioning committees, and fundraising program. Its stated goal was to support research to treat or cure ROP and related diseases, to explore and refine ROP treatments, and to support pharmaceutical products development in this field.

296. Supposedly, the ROPARD Fund funds research based on submission of project proposals for independent peer review in a competitive process, which are then referred to the ROPARD Board for consideration of support, with grants then being provided to eligible researchers at any eligible institution.

297. The Beaumont Foundation supports this Fund through both general solicitations of donations and dedicated fundraising events such as the Vision award dinner, annual golf outing, and the Walk for ROPARD.

298. These donations result in the issuance of tax receipts for donations to a not-for-profit.

299. After this competitive process, the awards are supposed to go to the appropriate institution. If they go to a Beaumont project, they are supposed to be accompanied by a letter of award, a one page progress report, and a transfer of appropriate funds from the ROPARD Fund to the appropriate Research Institute Account (RC).

300. However, Relator has come to see that the ROPARD Fund is actually nothing more than convenient conduit for fundraising for ROP research for ARC, using the good name and 501(c)(3) status of Beaumont to solicit tax-deductible donations.

301. The disbursement of funds from the ROPARD Fund appears rarely (if ever) to follow the peer-review process in a competitive fashion.

302. Dr. Trese, a well known ROP researcher and 100% private practitioner with ARC, was the signatory official for approval of expenditures from this Beaumont Foundation fund.

303. Trese often approved the funds to go directly to ARC with a check request or on the basis of an invoice.

304. Relator raised the issue internally because he was concerned that this same type of arrangement in some organizations in New York has resulted in the loss of not-for-profit status of the organization that permitted such channeling of resources to a private organization.

305. Dr. Trese's status as the signatory authority for Beaumont's ROPARD Fund (even though he is not an employee and has no official or administrative status) is at best a conflict of interest.

306. Furthermore, a Beaumont internal audit revealed that the Beaumont Foundation had no control over donor receipts submitted by mail (to an independent P.O. Box, subsequently sent to Beaumont by an outside representative) and did not monitor whether or not there was appropriate use of the restricted donations received by ROPARD, tasks which the Beaumont Foundation diligently carried out for other Foundation funds.

307. After the audit, Relator was told that these irregularities were being cleared up and that, as Vice President for Research, he would be replacing Trese in the process for approvals.

308. However, since this communication in March of 2007, Relator has not seen a single proposal, a single letter of grant award, or any documentation for fund usage – only requests to disburse funds.

309. Relator has repeatedly expressed his concerns to Margaret Casey, President of the Beaumont Foundation. He also brought his concerns to the CMO and the CEO, as well as the Chairman of the Research Institute Board of Governors, all to no avail.

310. These same ARC physicians used Beaumont resources to develop pharmaceutical products (plasmins), patented them privately without disclosure to Beaumont, assigned the patents to NuVue (a Vermont company set up by Drs. Williams and Trese), who then engaged in a licensing arrangement with a European company (Thrombogenics), all without Beaumont's knowledge.

311. When Relator discovered this issue he forced Beaumont leadership to recognize the problem, but their solution was to have Drs. Williams and Trese assign the patents and agreements to Beaumont, who then immediately reassigned them back to NuVue for some *de minimus* amount.

312. Trese and Relator had another run in over the matter of IRB review. In 2007, Dr. Trese applied to the FDA for a new drug application for use of a pharmaceutical agent, Macugen, for injection into the eye of newborns with Retinopathy of Prematurity.

313. Because of the status of these neonates as “vulnerable human subjects”, a new drug application was required rather than merely claiming off-label use. Of course, a research procedure such as injecting an experimental agent into the eye of newborns requires review and approval of the full IRB board.

314. Dr. Trese proceeded to inject five such neonates with Macugen, one before even submitting an application to Beaumont’s IRB, and four after submitting an application but prior to IRB final review and approval.

315. This was a dangerous and unethical case of research misconduct, and Relator made a full report to the Office of Human Research Protection (“OHRP”) at the Public Health Service, despite pushback from the medical administration.

316. Despite these major issues with Dr. Michael Trese related to the ROPARD fund, the NuVue development of Beaumont intellectual property, and the OHRP report of research misconduct, on July 26, 2010 Beaumont presented Dr. Trese the Beaumont-wide highest research award, the “Outstanding Medical Research Award: Seeker of Truth.”

317. At the same time, Dr. George Williams received the “Triple Threat” award for “Outstanding Academic Excellence” in the triple “threat” of clinical, research, and teaching.

Research Fraud Relating to Dr. Michael Borrelli

318. There is a single issue with one Radiation Oncology investigator that reveals the willingness of high level officials at Beaumont to commit blatant fraud. Dr. Michael Borrelli was working on NIH-funded projects related to radiation oncology. In 2002, by his own description, he experienced a cerebral bleed and became cognitively incapacitated. He experienced aphasia and was unable to read, write, or carry out his scientific functions for the grant.

319. Dr. Borrelli was a highly productive researcher with several patents and many ideas that the Beaumont leadership hoped would soon be generating royalties as new IP. Although the correct procedure would have been for Dr. Borrelli to take a medical leave during his recovery and then return to his responsibilities, Dr. Borrelli instead was continued on the NIH grants with his salary continuing to be provided from that source, even though he was incapable of carrying out his functions.

320. Borrelli informed Relator that both Drs. Martinez and Yan knew about this and approved of his continuing on the grants.

321. Relator had the opportunity to speak with Dr. Borrelli on several occasions in 2008, during discussions about potential commercialization of IP that Borrelli had developed while at Beaumont. He spoke quite freely with Relator about his cerebral bleed and emphasized to both Jack DeChellis and Relator that he

had been totally incapacitated and only recently had been able to function fully in his research.

322. The Research Institute has copies of all of Dr. Borrelli's signed time sheets during this period of incapacitation. It should be noted that with the type of aphasia Dr. Borrelli experienced, only automated writing functions, such as signing one's signature, are preserved sufficiently to be recognizable.

### **Theft of Government IP**

323. Image Guided Radiation Therapy ("IGRT"), or Cone Beam Technology, provides both imaging-guided targeting and radiation treatment in a single instrument. This provides more accurate radiation therapy, shorter duration of therapy, and multiple beam directions that produce less damage to adjacent normal tissue.

324. Beaumont's patented technology in this arena is licensed to Elekta (foreign company, discussed above) and is incorporated into the Elekta Synergy system, from which Beaumont receives royalties.

325. This technology was developed with funds from the following sources: (1) DOD (U.S. Army) Grants, including DAMD-17-98-8497 (Phase I), "An Online Tomographic Guidance System for Dose Escalation in Radiotherapy for Adenocarcinoma of the Prostate" (1 August 1998 to 30 April 2001), and DAMD-17-98-8497 (Phase II), an extension of the grant through 31 August 2003;

(2) NIH Grants, including 1R21AG019381-01, “High-Precision Image-Guided Radiotherapy of the Prostate” (15 May 2001 to 30 April 2005, relinquished 30 April 2002 to a Canadian University with a move of the PI), and 1R01CA089081-01, “Flat Panel Cone Beam CT for Image-Guided Radiotherapy” (1 March 2001 to 28 Feb 2005); (3) Elekta, provided to allow Beaumont to work on Cone Beam technology using equipment, input, and scientific assistance from Elekta; and (4) William Beaumont Hospital, which provided over \$5 million dollars of subsidy through the Research Institute from the late 1990s through 2005.

326. Under the Beaumont Intellectual Property policy, royalties generated from inventions created with hospital and RI support were to be divided with 25% to go to the inventors, 25% to go to the Beaumont Research Institute, 25% to go to the hospital, and 25% to go to the department that created the intellectual property at issue (here, Radiation Oncology).

327. In a supposed meeting of the Intellectual Property Committee that excluded representation from the RI (who was not even told about the meeting), Martinez asserted that the hospital directly provided the support to the project and that the RI provided no support, which justified a change of distribution of royalties to 25% to the inventors and 75% to Radiation Oncology.

328. This contention is not supported by the extensive evidence from Jack DeChellis’s accounting data from the Research Institute.

329. The original intention of this 75% distribution to Radiation Oncology was to permit all royalties to Beaumont to be channeled through a “special account” (slush fund) for discretionary use, while continuing the subsidy from the Research Institute of \$1 million per year. However, the Research Institute shut down such “discretionary” accounts and forced the 75% royalty distribution into the home account (RC) of Radiation Oncology, forcing the use of royalty funds to pay for and offset the former \$1 million per year subsidy from the Research Institute.

330. It should be noted, however, that if true that the **hospital** supported IGRT, it did so through use of clinical personnel whose salaries and effort roll up to the Medical Cost Report. In that case, the entire scheme constitutes a violation of Medicare reporting. It also amounts to the not-for-profit Beaumont Hospital providing funds to enrich a for-profit vendor (Elekta), with whom it had extensive multi-million dollar business dealings.

331. Drs. David Jaffray, John Wong, and Mark Siewardson, co-inventors of Beaumont’s components of the Cone Beam Technology, are holders of U.S. Patent 6,842,502, for which the Preliminary Patent application was filed February 18, 2001, followed by the full patent application. They were finally granted a U.S. Patent on January 11, 2005 and noted in several published manuscripts that their technology and inventions had been supported by the DOD and NIH grants above.

This strongly suggested that at least some of the Cone Beam Technology represented subject inventions.

332. In the 18-month progress report submitted for the U.S. Army grant on May 1, 2000, the Cone Beam patent application was listed as a “reportable outcome.” Similarly, on the final report submitted for the US Army grant in December 2001, the Cone Beam patent application was again listed as a “reportable outcome.”

333. Nevertheless, more than a year after the October 1, 2004 due date for the DD882 (Statement of Inventions), Jaffrey finally filed the DD882 on December 21, 2005 with a negative report, indicating that there were no subject inventions from the grant.

334. An e-mail from Dr. Mishra, the USAMRAA GOR to whom final reports from DOD research are processed, regarded this negative DD882 report as inappropriate because “Progress report review indicates that there was a patent application.”

335. Due to a series of USAMRAA changes and attempts from Radiation Oncology to postpone its response, this issue was not reported back to USAMRAA for several years and has not yet been resolved through the DOD.

336. In the meantime, a fully executed Elekta/William Beaumont Hospital licensing agreement was signed on December 16, 2003. It was authored by Chief

Legal Counsel Tom McAskin and Steven Oberholtzer of Brinks Hofer Gilson & Leone, who also represented Beaumont.

337. The agreement is in violation of FAR 52.227-11(i), which requires that subject inventions be commercialized through a U.S. company, with a preference for a U.S. small business. FAR 52.227-11(k)(4). Since it is unlikely a small business could adequately develop Cone Beam technology, it was incumbent upon Beaumont to first provide unlimited license to the contractor (DOD), as required, and then to develop the technology with a U.S. firm unless given permission by the DOD to do otherwise. (For example, Varian is a U.S. firm operating in this space, but is a fierce competitor of Elekta.)

338. Beaumont did neither, and knowingly crafted the illegal exclusive licensing agreement with its long-standing partner, Elekta.

339. The USAMRAA request for a clarification and accurate filing of DD882 threw a major monkey wrench into this matter. Although Relator pushed very hard for Beaumont to properly disclose the subject inventions, there was incredible reluctance and slowness in doing so. Ultimately, in his capacity as the William Beaumont Hospital's Institutional Official, Relator wrote a December 2, 2009 letter to Jennifer Shankle, Grants Specialist for the USAMRAA, to disclose these conclusions, along with a correction to DD882. He also wrote a letter to Basil Eldadah, M.D., Ph.D., Program Office of the Geriatrics Branch of the

Division of Geriatrics and Clinical Gerontology of the National Institutes of Aging, dated January 29, 2010, disclosing these same findings and requesting that these matters be resolved with the DOD playing the lead role. Beaumont to date has received no response from either office.

340. In summary, Beaumont researchers created a significant set of inventions using DOD support, NIH support, Elekta support, and Beaumont support (with the issue of research institute vs. hospital sources being of considerable significance with regard to possible inappropriate Medicare Cost Report roll ups). Despite knowing that the Principal Investigator, Dr. Jaffray, had reported the inventions and resultant patent application as derived from DOD and NIH support, and that the law requires that such inventions be commercialized by a U.S. firm, Beaumont moved forward with an exclusive licensing agreement with Elekta, which it should not have done.

341. Meanwhile, Elekta has made huge profits from this technology. Beaumont has made over \$10 million in royalties in the last six to seven years, and this technology has given this foreign company a lead in the field.

342. Moreover, it recently came to Relator's attention that both Alvaro Martinez, M.D., (Chief of Radiation Oncology) and John Wong, M.D., had at one time been on Elekta's Board, and that Di Yan, Ph.D., (lead physicist at Beaumont working on the Cone Beam Technology) currently sits on the Physics Scientific

advisory Board of Elekta as well. This raises further concerns that those doctors, who appear to have a financial relationship with Elekta, accepted Government funds to develop technology that should have been commercialized through a U.S. company, but instead exclusively licensed it to a foreign company with whom they had a close and long-standing relationship, giving that company a huge competitive advantage.

### **RETALIATION**

343. The more Relator spoke to Beaumont administration about the necessity of cleaning up the illegalities and kickback schemes at the hospital, the more tension was created between him and the other physicians and administrators.

344. Although Relator is in charge of the RI and its functions, he has been told repeatedly the issues he is raising are not his concern.

345. Relator's role at Beaumont has been continuously and increasingly marginalized due to his insistence that the laws and regulations of the United States be complied with, in violation of 31 U.S.C. § 3730(b).

### **COUNT I**

#### **Violation of 31 U.S.C. § 3729 – False Claims Act**

346. Relator hereby incorporates and realleges herein all other paragraphs as if fully set forth herein.

347. As set forth above, Defendants, by and through their agents, officers and employees, knowingly presented, or caused to be presented to the United

States Government numerous false or fraudulent claims for payment or approval, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

348. As set forth above, Defendants, by and through their agents, officers and employees, knowingly made, used, or caused to be made or used, false records or statements material to numerous false claims, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

349. As set forth above, Defendants, by and through their agents, officers and employees, conspired to commit various violations of 31 U.S.C. § 3729(a)(1)(A), (B), (D), and (G), in violation of 31 U.S.C. § 3729(a)(1)(C).

350. As set forth above, Defendants, by and through their agents, officers and employees, had possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivered, or caused to be delivered, less than all of that money or property, in violation of 31 U.S.C. § 3729(a)(1)(D).

351. As set forth above, Defendants, by and through their agents, officers and employees, knowingly made, used, or caused to be made or used a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the Government, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(G).

352. Due to Defendants' conduct, the United States has suffered substantial monetary damages.

353. The United States is entitled to treble damages based upon the amount of damage sustained by the United States as a result of Defendants' violations of the False Claims Act, 31 U.S.C. §§ 3729-3733, an amount that will be proven at trial.

354. The United States is entitled to a civil penalty of between \$5,500 and \$11,000 as required by 31 U.S.C. § 3729(a) for each of Defendants' fraudulent claims.

355. Relator is also entitled to reasonable attorneys' fees and costs, pursuant to 31 U.S.C. § 3730(d)(1).

**COUNT II**  
**Violation of Michigan Medicaid False Claims Act**

356. Relator hereby incorporates and realleges herein all other paragraphs as if fully set forth herein.

357. As set forth above, Defendants, by and through their agents, officers and employees, knowingly made or caused to be made a false statement or false representation of a material fact in an application for Medicaid benefits, in violation of M.C.L § 400.603(1).

358. As set forth above, Defendants, by and through their agents, officers and employees, knowingly made or caused to be made false statements or false

representations of materials fact for use in determining rights to Medicaid benefits, in violation of M.C.L § 400.603(2).

359. As set forth above, Defendants, by and through their agents, officers and employees, solicited, offered, and received kickbacks or bribes in connection with the furnishing of goods or services for which payment was to be made in whole or in part pursuant to a program established under Act No. 280 of the Public Acts of 1939, or made and/or received a payment or rebate of a fee or charge for referring an individual to another person for the furnishing of the goods and services, in violation of M.C.L § 400.604.

360. As set forth above, Defendants, by and through their agents, officers and employees, entered into an agreement, combination, or conspiracy to defraud the State of Michigan by obtaining, or aiding another to obtain, the payment or allowance of a false claim under the social welfare act, Act No. 280 of the Public Acts of 1939, as amended, in violation of M.C.L § 400.606.

361. As set forth above, Defendants, by and through their agents, officers and employees, made, presented, or caused to be made or presented to an employee or officer of the State of Michigan a claim under the social welfare act, 1939 PA 280, M.C.L. 400.1 to 400.119b, upon or against the State, knowing the claim to be false, in violation of M.C.L § 400.607(1).

362. As set forth above, Defendants, by and through their agents, officers and employees, knowingly made, used, or caused to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state pertaining to a claim presented under the social welfare act, in violation of M.C.L § 400.607(3).

363. Due to Defendants' conduct, the State of Michigan has suffered substantial monetary damages, in an amount that will be proven at trial. As a result, the State of Michigan is entitled to triple the amount of damages suffered by the State as a result of Defendants' conduct, pursuant to M.C.L § 400.612(1).

364. The State of Michigan is entitled to a civil penalty of between \$5,000 and \$10,000 as required by M.C.L § 400.612(1) for each of Defendants' fraudulent claims.

365. Relator is also entitled to necessary expenses, costs, reasonable attorney fees, pursuant to M.C.L § 400.610a(9).

**COUNT III**  
**Violation of 31 U.S.C. § 3730 – Retaliation**

366. Relator hereby incorporates and realleges herein all other paragraphs as if fully set forth herein.

367. Defendants violated Relator's rights pursuant to 31 U.S.C. § 3730(h) by retaliating against Relator for lawful acts done by Relator in furtherance of efforts to stop one or more violations alleged in this action.

368. As a result of Defendants' actions, Relator has suffered damages in an amount to be shown at trial.

**COUNT IV**  
**Violation of M.C.L § 400.610c– Retaliation**

369. Relator hereby incorporates and realleges herein all other paragraphs as if fully set forth herein.

370. Defendants violated Relator's rights pursuant to M.C.L § 400.610c by threatening, harassing, and in other ways discriminating because Relator engaged in lawful acts, including initiating, assisting in, or participating in the furtherance of an action under the Michigan Medicare False Claims Act.

371. As a result of Defendants' actions, Relator has suffered damages in an amount to be shown at trial.

**PRAYER FOR RELIEF**

**WHEREFORE**, Relator David L. Felten prays for judgment:

- (a) awarding the United States treble damages sustained by it for each of the false claims or overpayments that Defendants knowingly and improperly concealed so as to avoid its obligation to pay money to the Government;
- (b) awarding the United States a civil penalty of \$11,000 for each of the false claims;
- (c) awarding the State of Michigan treble damages sustained by it for each of the false claims or overpayments that Defendants knowingly and improperly concealed so as to avoid its obligation to pay money to the Government;
- (d) awarding the State of Michigan a civil penalty of \$10,000 for each of the false claims;

- (e) awarding Relator 30% of the proceeds of this action and any alternate remedy or the settlement of any such claim;
- (f) providing Relator all relief available for Defendants' violations of 31 U.S.C. § 3730(h) and M.C.L. § 400.610c;
- (g) awarding Relator special damages resulting from the retaliation;
- (h) awarding Relator his litigation costs and reasonable attorney's fees; and
- (i) granting such other relief as the Court may deem just and proper.

Respectfully submitted this 30th day of August, 2010,

s/ Julie K. Bracker  
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